(b) *Availability of transcripts.* CMS designates an official reporter for each hearing. Transcripts of testimony in hearings may be obtained from the official reporter by the parties and the public at rates not in excess of the maximum rates fixed by the contract between CMS and the reporter.

(c) *Correction of transcript.* Upon notice to all parties, the presiding officer may authorize corrections that affect substantive matters in the transcript.

§ 430.96 Record for decision.

The transcript of testimony, exhibits, and all papers and requests filed in the proceedings, except the correspondence section of the docket, including rulings and any recommended or initial decision constitute the exclusive record for decision.

§ 430.100 Posthearing briefs.

The presiding officer fixes the time for filing posthearing briefs, which may contain proposed findings of fact and conclusions of law. The presiding officer may also permit reply briefs.

§ 430.102 Decisions following hearing.

(a) *Administrator presides.* If the presiding officer is the Administrator, he or she issues the hearing decision within 60 days after expiration of the period for submission of posthearing briefs.

(b) *Administrator's designee presides.* If the presiding officer is other than the Administrator, the procedure is as follows:

(1) Upon expiration of the period allowed for submission of posthearing briefs, the presiding officer certifies the entire record, including his or her recommended findings and proposed decision, to the Administrator. The Administrator serves a copy of the recommended findings and proposed decision upon all parties and amici, if any.

(2) Any party may, within 20 days, file with the Administrator exceptions to the recommended findings and proposed decision and a supporting brief or statement.

(3) The Administrator reviews the recommended decision and, within 60 days of its issuance, issues his or her own decision.

(c) *Effect of Administrator's decision.* The decision of the Administrator under this section is the final decision of the Secretary and constitutes ''final agency action'' within the meaning of 5 U.S.C. 704 and a ''final determination'' within the meaning of section 1116(a)(3) of the Act and § 430.38. The Administrator's decision is promptly served on all parties and amici.

§ 430.104 Decisions that affect FFP.

(a) *Scope of decisions.* If the Administrator concludes that withholding of FFP is necessary because a State is out of compliance with Federal requirements, in accordance with § 430.35, the decision also specifies—

(1) Whether no further payments will be made to the State or whether payments will be limited to parts of the program not affected by the noncompliance; and

(2) The effective date of the decision to withhold.

(b) *Consultation.* The Administrator may ask the parties for recommendations or briefs or may hold conferences of the parties on the question of further payments to the State.

(c) *Effective date of decision.* The effective date of a decision to withhold Federal funds will not be earlier than the date of the Administrator's decision and will not be later than the first day of the next calendar quarter. The provisions of this section may not be waived under § 430.64.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

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AUTHORITY: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

SOURCE: 43 FR 45188, Sept. 29, 1978, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 431 appear at 75 FR 48852, Aug. 11, 2010.

§ 431.1 Purpose.

This part establishes State plan requirements for the designation, organization, and general administrative activities of a State agency responsible for operating the State Medicaid program, directly or through supervision of local administering agencies.

Subpart A—Single State Agency

§ 431.10 Single State agency.

(a) *Basis, purpose, and definitions.* (1) This section implements section 1902(a)(4) and (5) of the Act.

(2) For purposes of this part—

Appeals decision means a decision made by a hearing officer adjudicating a fair hearing under subpart E of this part.

Exchange has the meaning given to the term in 45 CFR 155.20.

Exchange appeals entity has the meaning given to the term ''appeals entity,'' as defined in 45 CFR 155.500.

Medicaid agency is the single State agency for the Medicaid program.

(b) *Designation and certification.* A State plan must—

(1) Specify a single State agency established or designated to administer or supervise the administration of the plan; and

(2) Include a certification by the State Attorney General, citing the

legal authority for the single State agency to—

(i) Administer or supervise the administration of the plan; and

(ii) Make rules and regulations that it follows in administering the plan or that are binding upon local agencies that administer the plan.

(3) The single State agency is responsible for determining eligibility for all individuals applying for or receiving benefits in accordance with regulations in part 435 of this chapter and for fair hearings filed in accordance with subpart E of this part.

(c) *Delegations.* (1) Subject to the requirement in paragraph (c)(2) of this section, the Medicaid agency—

(i)(A) May, in the approved state plan, delegate authority to determine eligibility for all or a defined subset of individuals to—

(*1*) The single State agency for the financial assistance program under title IV–A (in the 50 States or the District of Columbia), or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands;

(*2*) The Federal agency administering the supplemental security income program under title XVI of the Act; or

(*3*) The Exchange.

(B) Must in the approved state plan specify to which agency, and the individuals for which, authority to determine eligibility is delegated.

(ii) Delegate authority to conduct fair hearings under subpart E of this part for denials of eligibility for individuals whose income eligibility is determined based on the applicable modified adjusted gross income standard described in § 435.911(c) of this chapter, to an Exchange or Exchange appeals entity, provided that individuals who have requested a fair hearing of such a denial are given a choice to have their fair hearing instead conducted by the Medicaid agency.

(2) The Medicaid agency may delegate authority to make eligibility determinations or to conduct fair hearings under this section only to a government agency which maintains personnel standards on a merit basis.

(3) The Medicaid agency—

(i) Must ensure that any agency to which eligibility determinations or appeals decisions are delegated—

(A) Complies with all relevant Federal and State law, regulations and policies, including, but not limited to, those related to the eligibility criteria applied by the agency under part 435 of this chapter; prohibitions against conflicts of interest and improper incentives; and safeguarding confidentiality, including regulations set forth at subpart F of this part.

(B) Informs applicants and beneficiaries how they can directly contact and obtain information from the agency; and

(ii) Must exercise appropriate oversight over the eligibility determinations and appeals decisions made by such agencies to ensure compliance with paragraphs (c)(2) and (c)(3)(i) of this section and institute corrective action as needed, including, but not limited to, rescission of the authority delegated under this section.

(iii) If authority to conduct fair hearings is delegated to the Exchange or Exchange appeals entity under paragraph (c)(1)(ii) of this section, the agency may establish a review process whereby the agency may review fair hearing decisions made under that delegation, but that review will be limited to the proper application of federal and state Medicaid law and regulations, including sub-regulatory guidance and written interpretive policies, and must be conducted by an impartial official not directly involved in the initial determination.

(d) *Agreement with Federal, State or local entities making eligibility determinations or appeals decisions.* The plan must provide for written agreements between the Medicaid agency and the Exchange or any other State or local agency that has been delegated authority under paragraph (c)(1)(i) of this section to determine Medicaid eligibility and for written agreements between the agency and the Exchange or Exchange appeals entity that has been delegated authority to conduct Medicaid fair hearings under paragraph (c)(1)(ii) of this section. Such agreements must be available to the Secretary upon request and must include provisions for:

(1) The relationships and respective responsibilities of the parties, including but not limited to the respective

responsibilities to effectuate the fair hearing rules in subpart E of this part;

(2) Quality control and oversight by the Medicaid agency, including any reporting requirements needed to facilitate such control and oversight;

(3) Assurances that the entity to which authority to determine eligibility or conduct fair hearings will comply with the provisions set forth in paragraph (c)(3) of this section.

(4) For appeals, procedures to ensure that individuals have notice and a full opportunity to have their fair hearing conducted by either the Exchange or Exchange appeals entity or the Medicaid agency.

(e) *Authority of the single State agency.* The Medicaid agency may not delegate, to other than its own officials, the authority to supervise the plan or to develop or issue policies, rules, and regulations on program matters.

[44 FR 17930, Mar. 23, 1979, as amended at 77 FR 17202, Mar. 23, 2012; 78 FR 42300, July 15, 2013]

§ 431.11 Organization for administration.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes the general organization and staffing requirements for the Medicaid agency and the State plan.

(b) *Description of organization.* (1) The plan must include a description of the organization and functions of the Medicaid agency.

(2) When submitting a state plan amendment related to the designation, authority, organization or functions of the Medicaid agency, the Medicaid agency must provide an organizational chart reflecting the key components of the Medicaid agency and the functions each performs.

(c) *Eligibility determined or fair hearings decided by other entities.* If eligibility is determined or fair hearings decided by Federal or State entities other than the Medicaid agency or by local agencies under the supervision of other State agencies, the plan must include a description of the staff designated by those other entities and the functions they perform in carrying out their responsibilities.

[44 FR 17931, Mar. 23, 1979, as amended at 77 FR 17203, Mar. 23, 2012; 78 FR 42301, July 15, 2013]

§ 431.12 Medical care advisory committee.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State plan requirements for establishment of a committee to advise the Medicaid agency about health and medical care services.

(b) *State plan requirement.* A State plan must provide for a medical care advisory committee meeting the requirements of this section to advise the Medicaid agency director about health and medical care services.

(c) *Appointment of members.* The agency director, or a higher State authority, must appoint members to the advisory committee on a rotating and continuous basis.

(d) *Committee membership.* The committee must include—

(1) Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care;

(2) Members of consumers' groups, including Medicaid beneficiaries, and consumer organizations such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; and

(3) The director of the public welfare department or the public health department, whichever does not head the Medicaid agency.

(e) *Committee participation.* The committee must have opportunity for participation in policy development and program administration, including furthering the participation of beneficiary members in the agency program.

(f) *Committee staff assistance and financial help.* The agency must provide the committee with—

(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective recommendations; and

(2) Financial arrangements, if necessary, to make possible the participation of beneficiary members.

(g) *Federal financial participation.* FFP is available at 50 percent in expenditures for the committee's activities.

§ 431.15 Methods of administration.

A State plan must provide for methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the plan.

(Sec. 1902(a)(4) of the Act)

[44 FR 17931, Mar. 23, 1979]

§ 431.16 Reports.

A State plan must provide that the Medicaid agency will—

(a) Submit all reports required by the Secretary;

(b) Follow the Secretary's instructions with regard to the form and content of those reports; and

(c) Comply with any provisions that the Secretary finds necessary to verify and assure the correctness of the reports.

[44 FR 17931, Mar. 23, 1979]

§ 431.17 Maintenance of records.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes the kinds of records a Medicaid agency must maintain, the retention period, and the conditions under which microfilm copies may be substituted for original records.

(b) *Content of records.* A State plan must provide that the Medicaid agency will maintain or supervise the maintenance of the records necessary for the proper and efficient operation of the plan. The records must include—

(1) Individual records on each applicant and beneficiary that contain information on—

(i) Date of application;

(ii) Date of and basis for disposition;

(iii) Facts essential to determination of initial and continuing eligibility;

(iv) Provision of medical assistance;

(v) Basis for discontinuing assistance;

(vi) The disposition of income and eligibility verification information received under §§ 435.940 through 435.960 of this subchapter; and

(2) Statistical, fiscal, and other records necessary for reporting and accountability as required by the Secretary.

(c) *Retention of records.* The plan must provide that the records required under paragraph (b) of this section will be retained for the periods required by the Secretary.

(d) *Conditions for optional use of microfilm copies.* The agency may substitute certified microfilm copies for the originals of substantiating documents required for Federal audit and review, if the conditions in paragraphs (d)(1) through (4) of this section are met.

(1) The agency must make a study of its record storage and must show that the use of microfilm is efficient and economical.

(2) The microfilm system must not hinder the agency's supervision and control of the Medicaid program.

(3) The microfilm system must—

(i) Enable the State to audit the propriety of expenditures for which FFP is claimed; and

(ii) Enable the HHS Audit Agency and CMS to properly discharge their respective responsibilities for reviewing the manner in which the Medicaid program is being administered.

(4) The agency must obtain approval from the CMS regional office indicating—

(i) The system meets the conditions of paragraphs (d)(2) and (3) of this section; and

(ii) The microfilming procedures are reliable and are supported by an adequate retrieval system.

[44 FR 17931, Mar. 23, 1979, as amended at 51 FR 7210, Feb. 28, 1986]

§ 431.18 Availability of agency program manuals.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State plan requirements for facilitating access to Medicaid rules and policies by individuals outside the State Medicaid agency.

(b) *State plan requirements.* A State plan must provide that the Medicaid agency meets the requirements of paragraphs (c) through (g) of this section.

(c) *Availability in agency offices.* (1) The agency must maintain, in all its offices, copies of its current rules and

policies that affect the public, including those that govern eligibility, provision of medical assistance, covered services, and beneficiary rights and responsibilities.

(2) These documents must be available upon request for review, study, and reproduction by individuals during regular working hours of the agency.

(d) *Availability through other entities.* The agency must provide copies of its current rules and policies to—

(1) Public and university libraries;

(2) The local or district offices of the Bureau of Indian Affairs;

(3) Welfare and legal services offices; and

(4) Other entities that—

(i) Request the material in order to make it accessible to the public;

(ii) Are centrally located and accessible to a substantial number of the beneficiary population they serve; and

(iii) Agree to accept responsibility for filing all amendments or changes forwarded by the agency.

(e) *Availability in relation to fair hearings.* The agency must make available to an applicant or beneficiary, or his representative, a copy of the specific policy materials necessary—

(1) To determine whether to request a fair hearing; or

(2) To prepare for a fair hearing.

(f) *Availability for other purposes.* The agency must establish rules for making program policy materials available to individuals who request them for other purposes.

(g) *Charges for reproduction.* The agency must make copies of its program policy materials available without charge or at a charge related to the cost of reproduction.

[44 FR 17931, Mar. 23, 1979]

§ 431.20 Advance directives.

(a) *Basis and purpose.* This section, based on section 1902(a) (57) and (58) of the Act, prescribes State plan requirements for the development and distribution of a written description of State law concerning advance directives.

(b) A State Plan must provide that the State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the State law (whether statutory or as recognized by the courts of the State) concerning advance directives, as defined in § 489.100 of this chapter, to be distributed by Medicaid providers and health maintenance organizations (as specified in section 1903(m)(1)(A) of the Act) in accordance with the requirements under part 489, subpart I of this chapter. Revisions to the written descriptions as a result of changes in State law must be incorporated in such descriptions and distributed as soon as possible, but no later than 60 days from the effective date of the change in State law, to Medicaid providers and health maintenance organizations.

[57 FR 8202, Mar. 6, 1992, as amended at 60 FR 33293, June 27, 1995]

Subpart B—General Administrative Requirements

SOURCE: 56 FR 8847, Mar. 1, 1991, unless otherwise noted.

§ 431.40 Basis and scope.

(a) This subpart sets forth State plan requirements and exceptions that pertain to the following administrative requirements and provisions of the Act:

(1) Statewideness—section 1902(a)(1);

(2) Proper and efficient administration—section 1902(a)(4);

(3) Comparability of services—section 1902(a)(10) (B)–(E);

(4) Payment for services furnished outside the State—section 1902(a)(16);

(5) Free choice of providers—section 1902(a)(23);

(6) Special waiver provisions applicable to American Samoa and the Northern Mariana Islands—section 1902(j); and

(7) Exceptions to, and waiver of, State plan requirements—sections 1915 (a)–(c) and 1916 (a)(3) and (b)(3).

(b) Other applicable regulations include the following:

(1) Section 430.25 Waivers of State plan requirements.

(2) Section 440.250 Limits on comparability of services.

§ 431.50 Statewide operation.

(a) *Statutory basis.* Section 1902(a)(1) of the Act requires a State plan to be

in effect throughout the State, and section 1915 permits certain exceptions.

(b) *State plan requirements.* A State plan must provide that the following requirements are met:

(1) The plan will be in operation statewide through a system of local offices, under equitable standards for assistance and administration that are mandatory throughout the State.

(2) If administered by political subdivisions of the State, the plan will be mandatory on those subdivisions.

(3) The agency will ensure that the plan is continuously in operation in all local offices or agencies through—

(i) Methods for informing staff of State policies, standards, procedures, and instructions;

(ii) Systematic planned examination and evaluation of operations in local offices by regularly assigned State staff who make regular visits; and

(iii) Reports, controls, or other methods.

(c) *Exceptions.* (1) ''Statewide operation'' does not mean, for example, that every source of service must furnish the service State-wide. The requirement does not preclude the agency from contracting with a comprehensive health care organization (such as an HMO or a rural health clinic) that serves a specific area of the State, to furnish services to Medicaid beneficiaries who live in that area and chose to receive services from that HMO or rural health clinic. beneficiaries who live in other parts of the State may receive their services from other sources.

(2) Other allowable exceptions and waivers are set forth in §§ 431.54 and 431.55.

[56 FR 8847, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§ 431.51 Free choice of providers.

(a) *Statutory basis.* This section is based on sections 1902(a)(23), 1902(e)(2), and 1915(a) and (b) and 1932(a)(3) of the Act.

(1) Section 1902(a)(23) of the Act provides that beneficiaries may obtain services from any qualified Medicaid provider that undertakes to provide the services to them.

(2) Section 1915(a) of the Act provides that a State shall not be found out of compliance with section 1902(a)(23) solely because it imposes certain specified allowable restrictions on freedom of choice.

(3) Section 1915(b) of the Act authorizes waiver of the section 1902(a)(23) freedom of choice of providers requirement in certain specified circumstances, but not with respect to providers of family planning services.

(4) Section 1902(a)(23) of the Act provides that a beneficiary enrolled in a primary care case management system or Medicaid managed care organization (MCO) may not be denied freedom of choice of qualified providers of family planning services.

(5) Section 1902(e)(2) of the Act provides that an enrollee who, while completing a minimum enrollment period, is deemed eligible only for services furnished by or through the MCO or PCCM, may, as an exception to the deemed limitation, seek family planning services from any qualified provider.

(6) Section 1932(a) of the Act permits a State to restrict the freedom of choice required by section 1902(a)(23), under specified circumstances, for all services except family planning services.

(b) *State plan requirements.* A State plan, except the plan for Puerto Rico, the Virgin Islands, or Guam, must provide as follows:

(1) Except as provided under paragraph (c) of this section and part 438 of this chapter, a beneficiary may obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is—

(i) Qualified to furnish the services; and

(ii) Willing to furnish them to that particular beneficiary.

This includes an organization that furnishes, or arranges for the furnishing of, Medicaid services on a prepayment basis.

(2) A beneficiary enrolled in a primary care case-management system, a Medicaid MCO, or other similar entity will not be restricted in freedom of choice of providers of family planning services.

(c) *Exceptions.* Paragraph (b) of this section does not prohibit the agency from—

(1) Establishing the fees it will pay providers for Medicaid services;

(2) Setting reasonable standards relating to the qualifications of providers; or

(3) Subject to paragraph (b)(2) of this section, restricting beneficiaries' free choice of providers in accordance with one or more of the exceptions set forth in § 431.54, or under a waiver as provided in § 431.55; or

(4) Limiting the providers who are available to furnish targeted case management services defined in § 440.169 of this chapter to target groups that consist solely of individuals with developmental disabilities or with chronic mental illness. This limitation may only be permitted so that the providers of case management services for eligible individuals with developmental disabilities or with chronic mental illness are capable of ensuring that those individuals receive needed services.

(d) *Certification requirement*—(1) *Content of certification.* If a State implements a project under one of the exceptions allowed under § 431.54 (d), (e) or (f), it must certify to CMS that the statutory safeguards and requirements for an exception under section 1915(a) of the Act are met.

(2) *Timing of certification.* (i) For an exception under § 431.54(d), the State may not institute the project until after it has submitted the certification and CMS has made the findings required under the Act, and so notified the State.

(ii) For exceptions under § 431.54 (e) or (f), the State must submit the certificate by the end of the quarter in which it implements the project.

[56 FR 8847, Mar. 1, 1991, as amended at 67 FR 41094, June 14, 2002; 72 FR 68091, Dec. 4, 2007]

§ 431.52 Payments for services furnished out of State.

(a) *Statutory basis.* Section 1902(a)(16) of the Act authorizes the Secretary to prescribe State plan requirements for furnishing Medicaid to State residents who are absent from the State.

(b) *Payment for services.* A State plan must provide that the State will pay for services furnished in another State to the same extent that it would pay for services furnished within its boundaries if the services are furnished to a beneficiary who is a resident of the State, and any of the following conditions is met:

(1) Medical services are needed because of a medical emergency;

(2) Medical services are needed and the beneficiary's health would be endangered if he were required to travel to his State of residence;

(3) The State determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other State;

(4) It is general practice for beneficiaries in a particular locality to use medical resources in another State.

(c) *Cooperation among States.* The plan must provide that the State will establish procedures to facilitate the furnishing of medical services to individuals who are present in the State and are eligible for Medicaid under another State's plan.

§ 431.53 Assurance of transportation.

A State plan must—

(a) Specify that the Medicaid agency will ensure necessary transportation for beneficiaries to and from providers; and

(b) Describe the methods that the agency will use to meet this requirement.

[74 FR 31195, June 30, 2009]

§ 431.54 Exceptions to certain State plan requirements.

(a) *Statutory basis*—(1) Section 1915(a) of the Act provides that a State shall not be deemed to be out of compliance with the requirements of sections 1902(a)(1), (10), or (23) of the Act solely because it has elected any of the exceptions set forth in paragraphs (b) and (d) through (f) of this section.

(2) Section 1915(g) of the Act provides that a State may provide, as medical assistance, targeted case management services under the plan without regard to the requirements of sections 1902(a)(1) and 1902(a)(10)(B) of the Act.

(3) Section 1915(i) of the Act provides that a State may provide, as medical assistance, home and community-based services under an approved State plan amendment that meets certain requirements, without regard to the requirements of sections 1902(a)(10)(B) and

1902(a)(10)(C)(i)(III) of the Act, with respect to such services.

(b) *Additional services under a prepayment system.* If the Medicaid agency contracts on a prepayment basis with an organization that provides services additional to those offered under the State plan, the agency may restrict the provision of the additional services to beneficiaries who live in the area served by the organization and wish to obtain services from it.

(c) [Reserved]

(d) *Special procedures for purchase of medical devices and laboratory and X-ray tests.* The Medicaid agency may establish special procedures for the purchase of medical devices or laboratory and X-ray tests (as defined in § 440.30 of this chapter) through a competitive bidding process or otherwise, if the State assures, in the certification required under § 431.51(d), and CMS finds, as follows:

(1) Adequate services or devices are available to beneficiaries under the special procedures.

(2) Laboratory services are furnished through laboratories that meet the following requirements:

(i) They are independent laboratories, or inpatient or outpatient hospital laboratories that provide services for individuals who are not hospital patients, or physician laboratories that process at least 100 specimens for other physicians during any calendar year.

(ii) They meet the requirements of subpart M of part 405 or part 482 of this chapter.

(iii) Laboratories that require an interstate license under 42 CFR part 74 are licensed by CMS or receive an exemption from the licensing requirement by the College of American Pathologists. (Hospital and physician laboratories may participate in competitive bidding only with regard to services to non-hospital patients and other physicians' patients, respectively.)

(3) Any laboratory from which a State purchases services under this section has no more than 75 percent of its charges based on services to Medicare beneficiaries and Medicaid beneficiaries.

(e) *Lock-in of beneficiaries who overutilize Medicaid services.* If a Medicaid agency finds that a beneficiary has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State, the agency may restrict that beneficiary for a reasonable period of time to obtain Medicaid services from designated providers only. The agency may impose these restrictions only if the following conditions are met:

(1) The agency gives the beneficiary notice and opportunity for a hearing (in accordance with procedures established by the agency) before imposing the restrictions.

(2) The agency ensures that the beneficiary has reasonable access (taking into account geographic location and reasonable travel time) to Medicaid services of adequate quality.

(3) The restrictions do not apply to emergency services furnished to the beneficiary.

(f) *Lock-out of providers.* If a Medicaid agency finds that a Medicaid provider has abused the Medicaid program, the agency may restrict the provider, through suspension or otherwise, from participating in the program for a reasonable period of time.

Before imposing any restriction, the agency must meet the following conditions:

(1) Give the provider notice and opportunity for a hearing, in accordance with procedures established by the agency.

(2) Find that in a significant number or proportion of cases, the provider has:

(i) Furnished Medicaid services at a frequency or amount not medically necessary, as determined in accordance with utilization guidelines established by the agency; or

(ii) Furnished Medicaid services of a quality that does not meet professionally recognized standards of health care.

(3) Notify CMS and the general public of the restriction and its duration.

(4) Ensure that the restrictions do not result in denying beneficiaries reasonable access (taking into account geographic location: and reasonable travel time) to Medicaid services of adequate quality, including emergency services.

(g) *Targeted case management services.* The requirements of § 431.50(b) relating to the statewide operation of a State plan and § 440.240 of this chapter related to comparability of services do not apply with respect to targeted case management services defined in § 440.169 of this chapter.

(h) *State plan home and community-based services.* The requirements of § 440.240 of this chapter related to comparability of services do not apply with respect to State plan home and community-based services defined in § 440.182 of this chapter.

[56 FR 8847, Mar. 1, 1991, as amended at 72 FR 68091, Dec. 4, 2007; 79 FR 3028, Jan. 16, 2014]

§ 431.55 Waiver of other Medicaid requirements.

(a) *Statutory basis.* Section 1915(b) of the Act authorizes the Secretary to waive most requirements of section 1902 of the Act to the extent he or she finds proposed improvements or specified practices in the provision of services under Medicaid to be cost effective, efficient, and consistent with the objectives of the Medicaid program. Sections 1915 (f) and (h) prescribe how such waivers are to be approved, continued, monitored, and terminated. Section 1902(p)(2) of the Act conditions FFP in payments to an entity under a section 1915(b)(1) waiver on the State's provision for exclusion of certain entities from participation.

(b) *General requirements.* (1) General requirements for submittal of waiver requests, and the procedures that CMS follows for review and action on those requests are set forth in § 430.25 of this chapter.

(2) In applying for a waiver to implement an approvable project under paragraph (c), (d), (e), or (f) of this section, a Medicaid agency must document in the waiver request and maintain data regarding:

(i) The cost-effectiveness of the project;

(ii) The effect of the project on the accessibility and quality of services;

(iii) The anticipated impact of the project on the State's Medicaid program and;

(iv) Assurances that the restrictions on free choice of providers do not apply to family planning services.

(3) No waiver under this section may be granted for a period longer than 2 years, unless the agency requests a continuation of the waiver.

(4) CMS monitors the implementation of waivers granted under this section to ensure that requirements for such waivers are being met.

(i) If monitoring demonstrates that the agency is not in compliance with the requirements for a waiver under this section, CMS gives the agency notice and opportunity for a hearing.

(ii) If, after a hearing, CMS finds an agency to be out of compliance with the requirements of a waiver, CMS terminates the waiver and gives the agency a specified date by which it must demonstrate that it meets the applicable requirements of section 1902 of the Act.

(5) The requirements of section 1902(s) of the Act, with regard to adjustments in payments for inpatient hospital services furnished to infants who have not attained age 1 and to children who have not attained age 6 and who receive these services in disproportionate share hospitals, may not be waived under a section 1915(b) waiver.

(c) *Case-management system.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to implement a primary care case-management system or specialty physician services system.

(i) Under a primary care case-management system the agency assures that a specific person or persons or agency will be responsible for locating, coordinating, and monitoring all primary care or primary care and other medical care and rehabilitative services on behalf of a beneficiary. The person or agency must comply with the requirements set forth in part 438 of this chapter for primary care case management contracts and systems.

(ii) A specialty physician services system allows States to restrict beneficiaries of specialty services to designated providers of such services, even in the absence of a primary care case-management system.

(2) A waiver under this paragraph (c) may not be approved unless the State's request assures that the restrictions—

(i) Do not apply in emergency situations; and

(ii) Do not substantially impair access to medically necessary services of adequate quality.

(d) *Locality as central broker.* Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to allow a locality to act as a central broker to assist beneficiaries in selecting among competing health care plans. States must ensure that access to medically necessary services of adequate quality is not substantially impaired.

(1) A locality is any defined jurisdiction, e.g., district, town, city, borough, county, parish, or State.

(2) A locality may use any agency or agent, public or private, profit or nonprofit, to act on its behalf in carrying out its central broker function.

(e) *Sharing of cost savings.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to share with beneficiaries the cost savings resulting from the beneficiaries' use of more cost-effective medical care.

(2) Sharing is through the provision of additional services, including—

(i) Services furnished by a plan selected by the beneficiary; and

(ii) Services expressly offered by the State as an inducement for beneficiaries to participate in a primary care case-management system, a competing health care plan or other system that furnishes health care services in a more cost-effective manner.

(f) *Restriction of freedom of choice*—(1) Waiver of appropriate requirements of section 1902 of the Act may be authorized for States to restrict beneficiaries to obtaining services from (or through) qualified providers or practitioners that meet, accept, and comply with the State reimbursement, quality and utilization standards specified in the State's waiver request.

(2) An agency may qualify for a waiver under this paragraph (f) only if its applicable State standards are consistent with access, quality and efficient and economic provision of covered care and services and the restrictions it imposes—

(i) Do not apply to beneficiaries residing at a long-term care facility when a restriction is imposed unless the State arranges for reasonable and adequate beneficiary transfer.

(ii) Do not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services; and

(iii) Do not apply in emergency circumstances.

(3) Demonstrated effectiveness and efficiency refers to reducing costs or slowing the rate of cost increase and maximizing outputs or outcomes per unit of cost.

(4) The agency must make payments to providers furnishing services under a freedom of choice waiver under this paragraph (f) in accordance with the timely claims payment standards specified in §447.45 of this chapter for health care practitioners participating in the Medicaid program.

(g) [Reserved]

(h) *Waivers approved under section 1915(b)(1) of the Act*—(1) *Basic rules.* (i) An agency must submit, as part of it's waiver request, assurance that the entities described in paragraph (h)(2) of this section will be excluded from participation under an approved waiver.

(ii) FFP is available in payments to an entity that furnishes services under a section 1915(b)(1) waiver only if the agency excludes from participation any entity described in paragraph (h)(2) of this section.

(2) Entities that must be excluded. The agency must exclude an entity that meets any of the following conditions:

(i) Could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(ii) Has a substantial contractual relationship (direct or indirect) with an individual convicted of certain crimes, as described in section 1128(b)(8)(B) of the Act.

(iii) Employs or contracts directly or indirectly with one of the following:

(A) Any individual or entity that, under section 1128 or section 1128A of the Act, is precluded from furnishing health care, utilization review, medical social services, or administrative services.

(B) Any entity described in paragraph (h)(2)(i) of this section.

(3) Definitions. As used in this section, substantial contractual relationship means any contractual relationship that provides for one or more of the following services:

(i) The administration, management, or provision of medical services.

(ii) The establishment of policies, or the provision of operational support, for the administration, management, or provision of medical services.

[56 FR 8847, Mar. 1, 1991, as amended at 59 FR 4599, Feb. 1, 1994; 59 FR 36084, July 15, 1994; 67 FR 41094, June 14, 2002]

§ 431.56 Special waiver provisions applicable to American Samoa and the Northern Mariana Islands.

(a) *Statutory basis.* Section 1902(j) of the Act provides for waiver of all but three of the title XIX requirements, in the case of American Samoa and the Northern Mariana Islands.

(b) *Waiver provisions.* American Samoa or the Northern Mariana Islands may request, and CMS may approve, a waiver of any of the title XIX requirements except the following:

(1) The Federal medical assistance percentage specified in section 1903 of the Act and § 433.10(b) of this chapter.

(2) The limit imposed by section 1108(c) of the Act on the amount of Federal funds payable to American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition for Medicaid assistance.

(3) The requirement that payment be made only with respect to expenditure made by American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition of medical assistance.

Subpart C—Administrative Requirements: Provider Relations

§ 431.105 Consultation to medical facilities.

(a) *Basis and purpose.* This section implements section 1902(a)(24) of the Act, which requires that the State plan provide for consultative services by State agencies to certain institutions furnishing Medicaid services.

(b) *State plan requirements.* A State plan must provide that health agencies and other appropriate State agencies furnish consultative services to hospitals, nursing homes, home health agencies, clinics, and laboratories in order to assist these facilities to—

(1) Qualify for payments under the maternal and child health and crippled children's program (title V of the Act), Medicaid or Medicare;

(2) Establish and maintain fiscal records necessary for the proper and efficient administration of the Act; and

(3) Provide information needed to determine payments due under the Act for services furnished to beneficiaries.

(c) *State plan option: Consultation to other facilities.* The plan may provide that health agencies and other appropriate State agencies furnish consultation to other types of facilities if those facilities are specified in the plan and provide medical care to individuals receiving services under the programs specified in paragraph (b) of this section.

§ 431.107 Required provider agreement.

(a) *Basis and purpose.* This section sets forth State plan requirements, based on sections 1902(a)(4), 1902(a)(27), 1902(a)(57), and 1902(a)(58) of the Act, that relate to the keeping of records and the furnishing of information by all providers of services (including individual practitioners and groups of practitioners).

(b) *Agreements.* A State plan must provide for an agreement between the Medicaid agency and each provider or organization furnishing services under the plan in which the provider or organization agrees to:

(1) Keep any records necessary to disclose the extent of services the provider furnishes to beneficiaries;

(2) On request, furnish to the Medicaid agency, the Secretary, or the State Medicaid fraud control unit (if such a unit has been approved by the Secretary under § 455.300 of this chapter), any information maintained under paragraph (b)(1) of this section and any information regarding payments claimed by the provider for furnishing services under the plan;

(3) Comply with the disclosure requirements specified in part 455, subpart B of this chapter; and

(4) Comply with the advance directives requirements for hospitals, nursing facilities, providers of home health care and personal care services, hospices, and HMOs specified in part 489, subpart I, and §417.436(d) of this chapter.

(5)(i) Furnish to the State agency its National Provider Identifier (NPI) (if eligible for an NPI); and

(ii) Include its NPI on all claims submitted under the Medicaid program.

[44 FR 41644, July 17, 1979, as amended at 57 FR 8202, Mar. 6, 1992; 75 FR 24449, May 5, 2010]

§431.108 Effective date of provider agreements.

(a) *Applicability*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, this section applies to Medicaid provider agreements with entities that, as a basis for participation in Medicaid—

(i) Are subject to survey and certification by CMS or the State survey agency; or

(ii) Are deemed to meet Federal requirements on the basis of accreditation by an accrediting organization whose program has CMS approval at the time of accreditation survey and accreditation decision.

(2) *Exception.* A Medicaid provider agreement with a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(b) *All requirements are met on the date of survey.* The agreement is effective on the date the onsite survey (including the Life Safety Code survey if applicable) is completed, if on that date the provider meets—

(1) All applicable Federal requirements as set forth in this chapter; and

(2) Any other requirements imposed by the State for participation in the Medicaid program. (If the provider has a time-limited agreement, the new agreement is effective on the day following expiration of the current agreement.)

(c) *All requirements are not met on the date of survey.* If on the date the survey is completed the provider fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:

(1) An NF provider agreement is effective on the date on which—

(i) The NF is found to be in substantial compliance as defined in §488.301 of this chapter; and

(ii) CMS or the State survey agency receives from the NF, if applicable, an approvable waiver request.

(2) For an agreement with any other provider, the effective date is the earlier of the following:

(i) The date on which the provider meets all requirements.

(ii) The date on which a provider is found to meet all conditions of participation but has lower level deficiencies, and CMS or the State survey agency receives from the provider an acceptable plan of correction for the lower level deficiencies, or an approvable waiver request, or both. (The date of receipt is the effective date of the agreement, regardless of when CMS approves the plan of correction or waiver request, or both.)

(d) *Accredited provider requests participation in the Medicaid program*—(1) *General rule.* If a provider is currently accredited by a national accrediting organization whose program had CMS approval at the time of accreditation survey and accreditation decision, and on the basis of accreditation, CMS has deemed the provider to meet Federal requirements, the effective date depends on whether the provider is subject to requirements in addition to those included in the accrediting organization's approved program.

(i) *Provider subject to additional requirements.* For a provider that is subject to additional requirements, Federal or State, or both, the effective date is the date on which the provider meets all requirements, including the additional requirements.

(ii) *Provider not subject to additional requirements.* For a provider that is not subject to additional requirements, the effective date is the date of the provider's initial request for participation if on that date the provider met all Federal requirements.

(2) *Special rule: Retroactive effective date.* If the provider meets the requirements of paragraphs (d)(1) and (d)(1)(i) or (d)(1)(ii) of this section, the effective

date may be retroactive for up to one year, to encompass dates on which the provider furnished, to a Medicaid beneficiary, covered services for which it has not been paid.

[62 FR 43935, Aug. 18, 1997]

§ 431.110 Participation by Indian Health Service facilities.

(a) *Basis.* This section is based on section 1902(a)(4) of the Act, proper and efficient administration; 1902(a)(23), free choice of provider; and 1911, reimbursement of Indian Health Service facilities.

(b) *State plan requirements.* A State plan must provide that an Indian Health Service facility meeting State requirements for Medicaid participation must be accepted as a Medicaid provider on the same basis as any other qualified provider. However, when State licensure is normally required, the facility need not obtain a license but must meet all applicable standards for licensure. In determining whether a facility meets these standards, a Medicaid agency or State licensing authority may not take into account an absence of licensure of any staff member of the facility.

§ 431.115 Disclosure of survey information and provider or contractor evaluation.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(36) of the Act, which requires a State plan to provide that the State survey agency will make publicly available the findings from surveys of health care facilities, laboratories, agencies, clinics, or organizations; and

(2) Section 1106(d) of the Act, which places certain restrictions on the Medicaid agency's disclosure of contractor and provider evaluations.

(b) *Definition of State survey agency.* The State survey agency referred to in this section means the agency specified under section 1902(a)(9) of the Act as responsible for establishing and maintaining health standards for private or public institutions in which Medicaid beneficiaries may receive services.

(c) *State plan requirements.* A State plan must provide that the requirements of this section and § 488.325 of this chapter are met.

(d) *Disclosure procedure.* The Medicaid agency must have a procedure for disclosing pertinent findings obtained from surveys made by the State survey agency to determine if a health care facility, laboratory, agency, clinic or health care organization meets the requirements for participation in the Medicaid program.

(e) *Documents subject to disclosure.* Documents subject to disclosure include—

(1) Survey reports, except for Joint Commission on the Accreditation of Hospitals reports prohibited from disclosure under § 422.426(b)(2) of this chapter;

(2) Official notifications of findings based on survey reports:

(3) Pertinent parts of written documents furnished by the health care provider to the survey agency that relate to the reports and findings; and

(4) Ownership and contract information as specified in § 455.104 of this subchapter.

(f) *Availability for inspection and copy of statements listing deficiencies.* The disclosure procedure must provide that the State survey agency will—

(1) Make statements of deficiencies based on the survey reports available for inspection and copying in both the public assistance office and the Social Security Administration district office serving the area where the provider is located; and

(2) Submit to the Regional Medicaid Director, through the Medicaid agency, a plan for making those findings available in other public assistance offices in standard metropolitian statistical areas where this information would be helpful to persons likely to use the health care provider's services.

(g) *When documents must be made available.* The disclosure procedure must provide that the State survey agency will—

(1) Retain in the survey agency office and make available upon request survey reports and current and accurate ownership information; and

(2) Make available survey reports, findings, and deficiency statements immediately upon determining that a health care provider is eligible to begin

or continue participation in the Medicaid program, or within 90 days after completion of the survey, whichever occurs first.

(h) *Evaluation reports on providers and contractors.* (1) If the Secretary sends the following reports to the Medicaid agency, the agency must meet the requirements of paragraphs (h) (2) and (3) of this section in releasing them:

(i) Individual contractor performance reviews and other formal performance evaluations of carriers, intermediaries, and State agencies, including the reports of followup reviews;

(ii) Comparative performance evaluations of those contractors, including comparisons of either overall performance or of any particular aspect of contractor operations; and

(iii) Program validation survey reports and other formal performance evaluations of providers, including the reports of followup reviews.

(2) The agency must not make the reports public until—

(i) The contractor or provider has had a reasonable opportunity, not to exceed 30 days, to comment on them; and

(ii) Those comments have been incorporated in the report.

(3) The agency must ensure that the reports contain no identification of individual patients, individual health care practitioners or other individuals.

[43 FR 45188, Sept. 29, 1978, as amended at 44 FR 41644, July 17, 1979; 59 FR 56232, Nov. 10, 1994]

§431.120 State requirements with respect to nursing facilities.

(a) *State plan requirements.* A State plan must—

(1) Provide that the requirements of subpart D of part 483 of this chapter are met; and

(2) Specify the procedures and rules that the State follows in carrying out the specified requirements, including review and approval of State-operated programs.

(3) To an NF or ICF/IID that is dissatisfied with a determination as to the effective date of its provider agreement.

(b) *Basis and scope of requirements.* The requirements set forth in part 483 of this chapter pertain to the following aspects of nursing facility services and are required by the indicated sections of the Act.

(1) Nurse aide training and competency programs, and evaluation of nurse aide competency (1919(e)(1) of the Act).

(2) Nurse aide registry (1919(e)(2) of the Act).

[56 FR 48918, Sept. 26, 1991, as amended at 62 FR 43935, Aug. 18, 1997]

Subpart D—Appeals Process for NFs and ICFs/IID

SOURCE: 44 FR 9753, Feb. 15, 1979, unless otherwise noted.

§431.151 Scope and applicability.

(a) *General rules.* This subpart sets forth the appeals procedures that a State must make available as follows:

(1) To a nursing facility (NF) that is dissatisfied with a State's finding of noncompliance that has resulted in one of the following adverse actions:

(i) Denial or termination of its provider agreement.

(ii) Imposition of a civil money penalty or other alternative remedy.

(2) To an intermediate care facility for Individuals with Intellectual Disabilities (ICF/IID) that is dissatisfied with a State's finding of noncompliance that has resulted in the denial, termination, or nonrenewal of its provider agreement.

(3) To an NF or ICF/IID that is dissatisfied with a determination as to the effective date of its provider agreement.

(b) *Special rules.* This subpart also sets forth the special rules that apply in particular circumstances, the limitations on the grounds for appeal, and the scope of review during a hearing.

[61 FR 32348, June 24, 1996, as amended at 62 FR 43935, Aug. 18, 1997]

§431.152 State plan requirements.

The State plan must provide for appeals procedures that, as a minimum, satisfy the requirements of §§431.153 and 431.154.

[59 FR 56232, Nov. 10, 1994, as amended at 61 FR 32348, June 24, 1996]

§ 431.153 Evidentiary hearing.

(a) *Right to hearing.* Except as provided in paragraph (b) of this section, and subject to the provisions of paragraphs (c) through (j) of this section, the State must give the facility a full evidentiary hearing for any of the actions specified in § 431.151.

(b) *Limit on grounds for appeal.* The following are not subject to appeal:

(1) The choice of sanction or remedy.

(2) The State monitoring remedy.

(3) [Reserved]

(4) The level of noncompliance found by a State except when a favorable final administrative review decision would affect the range of civil money penalty amounts the State could collect.

(5) A State survey agency's decision as to when to conduct an initial survey of a prospective provider.

(c) *Notice of deficiencies and impending remedies.* The State must give the facility a written notice that includes:

(1) The basis for the decision; and

(2) A statement of the deficiencies on which the decision was based.

(d) *Request for hearing.* The facility or its legal representative or other authorized official must file written request for hearing within 60 days of receipt of the notice of adverse action.

(e) *Special rules: Denial, termination or nonrenewal of provider agreement*—(1) *Appeal by an ICF/IID.* If an ICF/IID requests a hearing on denial, termination, or nonrenewal of its provider agreement—

(i) The evidentiary hearing must be completed either before, or within 120 days after, the effective date of the adverse action; and

(ii) If the hearing is made available only after the effective date of the action, the State must, before that date, offer the ICF/IID an informal reconsideration that meets the requirements of § 431.154.

(2) *Appeal by an NF.* If an NF requests a hearing on the denial or termination of its provider agreement, the request does not delay the adverse action and the hearing need not be completed before the effective date of the action.

(f) *Special rules: Imposition of remedies.* If a State imposes a civil money penalty or other remedies on an NF, the following rules apply:

(1) *Basic rule.* Except as provided in paragraph (f)(2) of this section (and notwithstanding any provision of State law), the State must impose all remedies timely on the NF, even if the NF requests a hearing.

(2) *Exception.* The State may not collect a civil money penalty until after the 60-day period for request of hearing has elapsed or, if the NF requests a hearing, until issuance of a final administrative decision that supports imposition of the penalty.

(g) *Special rules: Dually participating facilities.* If an NF is also participating or seeking to participate in Medicare as an SNF, and the basis for the State's denial or termination of participation in Medicaid is also a basis for denial or termination of participation in Medicare, the State must advise the facility that—

(1) The appeals procedures specified for Medicare facilities in part 498 of this chapter apply; and

(2) A final decision entered under the Medicare appeals procedures is binding for both programs.

(h) *Special rules: Adverse action by CMS.* If CMS finds that an NF is not in substantial compliance and either terminates the NF's Medicaid provider agreement or imposes alternative remedies on the NF (because CMS's findings and proposed remedies prevail over those of the State in accordance with § 488.452 of this chapter), the NF is entitled only to the appeals procedures set forth in part 498 of this chapter, instead of the procedures specified in this subpart.

(i) *Required elements of hearing.* The hearing must include at least the following:

(1) Opportunity for the facility—

(i) To appear before an impartial decision-maker to refute the finding of noncompliance on which the adverse action was based;

(ii) To be represented by counsel or other representative; and

(iii) To be heard directly or through its representative, to call witnesses, and to present documentary evidence.

(2) A written decision by the impartial decision-maker, setting forth the reasons for the decision and the evidence on which the decision is based.

(j) *Limits on scope of review: Civil money penalty cases.* In civil money penalty cases—

(1) The State's finding as to a NF's level of noncompliance must be upheld unless it is clearly erroneous; and

(2) The scope of review is as set forth in § 488.438(e) of this chapter.

[61 FR 32348, June 24, 1996, as amended at 62 FR 43935, Aug. 18, 1997; 64 FR 39937, July 23, 1999]

§ 431.154 Informal reconsideration for ICFs/IID.

The informal reconsideration must, at a minimum, include—

(a) Written notice to the facility of the denial, termination or nonrenewal and the findings upon which it was based;

(b) A reasonable opportunity for the facility to refute those findings in writing, and

(c) A written affirmation or reversal of the denial, termination, or nonrenewal.

[44 FR 9753, Feb. 15, 1979, as amended at 59 FR 56233, Nov. 10, 1994; 61 FR 32349, June 24, 1996]

Subpart E—Fair Hearings for Applicants and Beneficiaries

SOURCE: 44 FR 17932, Mar. 29, 1979, unless otherwise noted.

GENERAL PROVISIONS

§ 431.200 Basis and scope.

This subpart—

(a) Implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly;

(b) Prescribes procedures for an opportunity for a hearing if the State agency or PAHP takes action, as stated in this subpart, to suspend, terminate, or reduce services, or an MCO or PIHP takes action under subpart F of part 438 of this chapter; and

(c) Implements sections 1919(f)(3) and 1919(e)(7)(F) of the Act by providing an appeals process for any person who—

(1) Is subject to a proposed transfer or discharge from a nursing facility; or

(2) Is adversely affected by the preadmission screening or the annual resident review that are required by section 1919(e)(7) of the Act.

[67 FR 41094, June 14, 2002]

§ 431.201 Definitions.

For purposes of this subpart:

Action means a termination, suspension, or reduction of Medicaid eligibility or covered services. It also means determinations by skilled nursing facilities and nursing facilities to transfer or discharge residents and adverse determinations made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

Adverse determination means a determination made in accordance with sections 1919(b)(3)(F) or 1919(e)(7)(B) of the Act that the individual does not require the level of services provided by a nursing facility or that the individual does or does not require specialized services.

Date of action means the intended date on which a termination, suspension, reduction, transfer or discharge becomes effective. It also means the date of the determination made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

De novo hearing means a hearing that starts over from the beginning.

Evidentiary hearing means a hearing conducted so that evidence may be presented.

Notice means a written statement that meets the requirements of § 431.210.

Request for a hearing means a clear expression by the applicant or beneficiary, or his authorized representative, that he wants the opportunity to present his case to a reviewing authority.

Send means deliver by mail or in electronic format consistent with § 435.918 of this chapter.

Service authorization request means a managed care enrollee's request for the provision of a service.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 67 FR 41095, June 14, 2002; 78 FR 42301, July 15, 2013]

§ 431.202 State plan requirements.

A State plan must provide that the requirements of §§ 431.205 through 431.246 of this subpart are met.

§ 431.205 Provision of hearing system.

(a) The Medicaid agency must be responsible for maintaining a hearing system that meets the requirements of this subpart.

(b) The State's hearing system must provide for—

(1) A hearing before—

(i) The Medicaid agency; or

(ii) For the denial of eligibility for individuals whose income eligibility is determined based on the applicable modified adjusted gross income standard described in§ 435.911(c) of this chapter, the Exchange or Exchange appeals entity to which authority to conduct fair hearings has been delegated under § 431.10(c)(1)(ii), provided that individuals who have requested a fair hearing are given the choice to have their fair hearing conducted instead by the Medicaid agency; at state option the Exchange or Exchange appeals entity decision may be subject to review by the Medicaid agency in accordance with § 431.10(c)(3)(iii); or

(2) An evidentiary hearing at the local level, with a right of appeal to the Medicaid agency.

(c) The agency may offer local hearings in some political subdivisions and not in others.

(d) The hearing system must meet the due process standards set forth in *Goldberg v. Kelly*, 397 U.S. 254 (1970), and any additional standards specified in this subpart.

[44 FR 17932, Mar. 29, 1979, as amended at 78 FR 42301, July 15, 2013]

§ 431.206 Informing applicants and beneficiaries.

(a) The agency must issue and publicize its hearing procedures.

(b) The agency must, at the time specified in paragraph (c) of this section, inform every applicant or beneficiary in writing—

(1) Of his right to a hearing;

(2) Of the method by which he may obtain a hearing; and

(3) That he may represent himself or use legal counsel, a relative, a friend, or other spokesman.

(c) The agency must provide the information required in paragraph (b) of this section—(1) At the time that the individual applies for Medicaid;

(2) At the time of any action affecting his or her claim;

(3) At the time a skilled nursing facility or a nursing facility notifies a resident in accordance with § 483.12 of this chapter that he or she is to be transferred or discharged; and

(4) At the time an individual receives an adverse determination by the State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

(d) If, in accordance with § 431.10(c)(1)(ii), the agency has delegated authority to the Exchange or Exchange appeals entity to conduct the fair hearing, the agency must inform the individual in writing that—

(1) He or she has the right to have his or her hearing before the agency, instead of the Exchange or the Exchange appeals entity; and

(2) The method by which the individual may make such election;

(e) The information required under this section may be provided in electronic format in accordance with § 435.918 of this chapter.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993; 78 FR 42301, July 15, 2013]

NOTICE

§ 431.210 Content of notice.

A notice required under § 431.206 (c)(2), (c)(3), or (c)(4) of this subpart must contain—

(a) A statement of what action the State, skilled nursing facility, or nursing facility intends to take;

(b) The reasons for the intended action;

(c) The specific regulations that support, or the change in Federal or State law that requires, the action;

(d) An explanation of—

(1) The individual's right to request an evidentiary hearing if one is available, or a State agency hearing; or

(2) In cases of an action based on a change in law, the circumstances under which a hearing will be granted; and

(e) An explanation of the circumstances under which Medicaid is continued if a hearing is requested.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992]

§ 431.211 Advance notice.

The State or local agency must send a notice at least 10 days before the date of action, except as permitted under §§ 431.213 and 431.214.

[78 FR 42301, July 15, 2013]

§ 431.213 Exceptions from advance notice.

The agency may send a notice not later than the date of action if—

(a) The agency has factual information confirming the death of a beneficiary;

(b) The agency receives a clear written statement signed by a beneficiary that—

(1) He no longer wishes services; or

(2) Gives information that requires termination or reduction of services and indicates that he understands that this must be the result of supplying that information;

(c) The beneficiary has been admitted to an institution where he is ineligible under the plan for further services;

(d) The beneficiary's whereabouts are unknown and the post office returns agency mail directed to him indicating no forwarding address (See § 431.231 (d) of this subpart for procedure if the beneficiary's whereabouts become known);

(e) The agency establishes the fact that the beneficiary has been accepted for Medicaid services by another local jurisdiction, State, territory, or commonwealth;

(f) A change in the level of medical care is prescribed by the beneficiary's physician;

(g) The notice involves an adverse determination made with regard to the preadmission screening requirements of section 1919(e)(7) of the Act; or

(h) The date of action will occur in less than 10 days, in accordance with § 483.12(a)(5)(ii), which provides exceptions to the 30 days notice requirements of § 483.12(a)(5)(i).

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993; 78 FR 42301, July 15, 2013]

§ 431.214 Notice in cases of probable fraud.

The agency may shorten the period of advance notice to 5 days before the date of action if—

(a) The agency has facts indicating that action should be taken because of probable fraud by the beneficiary; and

(b) The facts have been verified, if possible, through secondary sources.

RIGHT TO HEARING

§ 431.220 When a hearing is required.

(a) The State agency must grant an opportunity for a hearing to the following:

(1) Any applicant who requests it because his claim for services is denied or is not acted upon with reasonable promptness.

(2) Any beneficiary who requests it because he or she believes the agency has taken an action erroneously.

(3) Any resident who requests it because he or she believes a skilled nursing facility or nursing facility has erroneously determined that he or she must be transferred or discharged.

(4) Any individual who requests it because he or she believes the State has made an erroneous determination with regard to the preadmission and annual resident review requirements of section 1919(e)(7) of the Act.

(5) Any MCO or PIHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

(6) Any PAHP enrollee who has an action as stated in this subpart.

(7) Any enrollee who is entitled to a hearing under subpart B of part 438 of this chapter.

(b) The agency need not grant a hearing if the sole issue is a Federal or State law requiring an automatic change adversely affecting some or all beneficiaries.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 431.221 Request for hearing.

(a) The agency may require that a request for a hearing be in writing.

(b) The agency may not limit or interfere with the applicant's or beneficiary's freedom to make a request for a hearing.

(c) The agency may assist the applicant or beneficiary in submitting and processing his request.

(d) The agency must allow the applicant or beneficiary a reasonable time, not to exceed 90 days from the date that notice of action is mailed, to request a hearings.

§ 431.222 Group hearings.

The agency—

(a) May respond to a series of individual requests for hearing by conducting a single group hearing;

(b) May consolidate hearings only in cases in which the sole issue involved is one of Federal or State law or policy;

(c) Must follow the policies of this subpart and its own policies governing hearings in all group hearings; and

(d) Must permit each person to present his own case or be represented by his authorized representative.

§ 431.223 Denial or dismissal of request for a hearing.

The agency may deny or dismiss a request for a hearing if—

(a) The applicant or beneficiary withdraws the request in writing; or

(b) The applicant or beneficiary fails to appear at a scheduled hearing without good cause.

PROCEDURES

§ 431.230 Maintaining services.

(a) If the agency sends the 10-day or 5-day notice as required under § 431.211 or § 431.214 of this subpart, and the beneficiary requests a hearing before the date of action, the agency may not terminate or reduce services until a decision is rendered after the hearing unless—

(1) It is determined at the hearing that the sole issue is one of Federal or State law or policy; and

(2) The agency promptly informs the beneficiary in writing that services are to be terminated or reduced pending the hearing decision.

(b) If the agency's action is sustained by the hearing decision, the agency may institute recovery procedures against the applicant or beneficiary to recoup the cost of any services furnished the beneficiary, to the extent they were furnished solely by reason of this section.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980; 78 FR 42302, July 15, 2013]

§ 431.231 Reinstating services.

(a) The agency may reinstate services if a beneficiary requests a hearing not more than 10 days after the date of action.

(b) The reinstated services must continue until a hearing decision unless, at the hearing, it is determined that the sole issue is one of Federal or State law or policy.

(c) The agency must reinstate and continue services until a decision is rendered after a hearing if—

(1) Action is taken without the advance notice required under § 431.211 or § 431.214 of this subpart;

(2) The beneficiary requests a hearing within 10 days from the date that the individual receives the notice of action. The date on which the notice is received is considered to be 5 days after the date on the notice, unless the beneficiary shows that he or she did not receive the notice within the 5-day period; and

(3) The agency determines that the action resulted from other than the application of Federal or State law or policy.

(d) If a beneficiary's whereabouts are unknown, as indicated by the return of unforwardable agency mail directed to him, any discontinued services must be reinstated if his whereabouts become known during the time he is eligible for services.

[44 FR 17932, Mar. 29, 1979, as amended at 78 FR 42302, July 15, 2013]

§ 431.232 Adverse decision of local evidentiary hearing.

If the decision of a local evidentiary hearing is adverse to the applicant or beneficiary, the agency must—

(a) Inform the applicant or beneficiary of the decision;

(b) Inform the applicant or beneficiary that he has the right to appeal the decision to the State agency, in writing, within 15 days of the mailing of the notice of the adverse decision;

(c) Inform the applicant or beneficiary of his right to request that his appeal be a *de novo* hearing; and

(d) Discontinue services after the adverse decision.

§ 431.233 State agency hearing after adverse decision of local evidentiary hearing.

(a) Unless the applicant or beneficiary specifically requests a *de novo* hearing, the State agency hearing may consist of a review by the agency hearing officer of the record of the local evidentiary hearing to determine whether the decision of the local hearing officer was supported by substantial evidence in the record.

(b) A person who participates in the local decision being appealed may not participate in the State agency hearing decision.

§ 431.240 Conducting the hearing.

(a) All hearings must be conducted—

(1) At a reasonable time, date, and place;

(2) Only after adequate written notice of the hearing; and

(3) By one or more impartial officials or other individuals who have not been directly involved in the initial determination of the action in question.

(b) If the hearing involves medical issues such as those concerning a diagnosis, an examining physician's report, or a medical review team's decision, and if the hearing officer considers it necessary to have a medical assessment other than that of the individual involved in making the original decision, such a medical assessment must be obtained at agency expense and made part of the record.

(c) A hearing officer must have access to agency information necessary to issue a proper hearing decision, including information concerning State policies and regulations.

[44 FR 17932, Mar. 29, 1979, as amended at 78 FR 42302, July 15, 2013]

§ 431.241 Matters to be considered at the hearing.

The hearing must cover—

(a) Agency action or failure to act with reasonable promptness on a claim for services, including both initial and subsequent decisions regarding eligibility;

(b) Agency decisions regarding changes in the type or amount of services;

(c) A decision by a skilled nursing facility or nursing facility to transfer or discharge a resident; and

(d) A State determination with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

[57 FR 56505, Nov. 30, 1992]

§ 431.242 Procedural rights of the applicant or beneficiary.

The applicant or beneficiary, or his representative, must be given an opportunity to—

(a) Examine at a reasonable time before the date of the hearing and during the hearing:

(1) The content of the applicant's or beneficiary's case file; and

(2) All documents and records to be used by the State or local agency or the skilled nursing facility or nursing facility at the hearing;

(b) Bring witnesses;

(c) Establish all pertinent facts and circumstances;

(d) Present an argument without undue interference; and

(e) Question or refute any testimony or evidence, including opportunity to confront and cross-examine adverse witnesses.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56506, Nov. 30, 1992]

§ 431.243 Parties in cases involving an eligibility determination.

If the hearing involves an issue of eligibility and the Medicaid agency is not responsible for eligibility determinations, the agency that is responsible for determining eligibility must participate in the hearing.

§ 431.244 Hearing decisions.

(a) Hearing recommendations or decisions must be based exclusively on evidence introduced at the hearing.

(b) The record must consist only of—

(1) The transcript or recording of testimony and exhibits, or an official report containing the substance of what happened at the hearing;

(2) All papers and requests filed in the proceeding; and

(3) The recommendation or decision of the hearing officer.

(c) The applicant or beneficiary must have access to the record at a convenient place and time.

(d) In any evidentiary hearing, the decision must be a written one that—

(1) Summarizes the facts; and

(2) Identifies the regulations supporting the decision.

(e) In a *de novo* hearing, the decision must—

(1) Specify the reasons for the decision; and

(2) Identify the supporting evidence and regulations.

(f) The agency must take final administrative action as follows:

(1) Ordinarily, within 90 days from the earlier of the following:

(i) The date the enrollee filed an MCO or PIHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing; or

(ii) If permitted by the State, the date the enrollee filed for direct access to a State fair hearing.

(2) As expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, from the MCO or PIHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PIHP—

(i) Meets the criteria for expedited resolution as set forth in §438.410(a) of this chapter, but was not resolved within the timeframe for expedited resolution; or

(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.

(3) If the State agency permits direct access to a State fair hearing, as expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, directly from an MCO or PIHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in §438.410(a) of this chapter.

(g) The public must have access to all agency hearing decisions, subject to the requirements of subpart F of this part for safeguarding of information.

[44 FR 17932, Mar. 29, 1979, as amended at 67 FR 41095, June 14, 2002]

§ 431.245 Notifying the applicant or beneficiary of a State agency decision.

The agency must notify the applicant or beneficiary in writing of—

(a) The decision; and

(b) His right to request a State agency hearing or seek judicial review, to the extent that either is available to him.

§ 431.246 Corrective action.

The agency must promptly make corrective payments, retroactive to the date an incorrect action was taken, and, if appropriate, provide for admission or readmission of an individual to a facility if—

(a) The hearing decision is favorable to the applicant or beneficiary; or

(b) The agency decides in the applicant's or beneficiary's favor before the hearing.

[57 FR 56506, Nov. 30, 1992]

FEDERAL FINANCIAL PARTICIPATION

§ 431.250 Federal financial participation.

FFP is available in expenditures for—

(a) Payments for services continued pending a hearing decision;

(b) Payments made—

(1) To carry out hearing decisions; and

(2) For services provided within the scope of the Federal Medicaid program and made under a court order.

(c) Payments made to take corrective action prior to a hearing;

(d) Payments made to extend the benefit of a hearing decision or court order to individuals in the same situation as those directly affected by the decision or order;

(e) Retroactive payments under paragraphs (b), (c), and (d) of this section in accordance with applicable Federal policies on corrective payments; and

(f) Administrative costs incurred by the agency for—

(1) Transportation for the applicant or beneficiary, his representative, and witnesses to and from the hearing;

(2) Meeting other expenses of the applicant or beneficiary in connection with the hearing;

(3) Carrying out the hearing procedures, including expenses of obtaining the additional medical assessment specified in § 431.240 of this subpart; and

(4) Hearing procedures for Medicaid and non-Medicaid individuals appealing transfers, discharges and determinations of preadmission screening and annual resident reviews under part 483, subparts C and E of this chapter.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980; 57 FR 56506, Nov. 30, 1992]

Subpart F—Safeguarding Information on Applicants and Beneficiaries

SOURCE: 44 FR 17934, Mar. 29, 1979, unless otherwise noted.

§ 431.300 Basis and purpose.

(a) Section 1902(a)(7) of the Act requires that a State plan must provide safeguards that restrict the use or disclosure of information concerning applicants and beneficiaries to purposes directly connected with the administration of the plan. This subpart specifies State plan requirements, the types of information to be safeguarded, the conditions for release of safeguarded information, and restrictions on the distribution of other information.

(b) For purposes of this subpart, information concerning an applicant or beneficiary includes information on a non-applicant, as defined in § 435.4 of this subchapter.

(c) Section 1137 of the Act, which requires agencies to exchange information to verify the income and eligibility of applicants and beneficiaries (see § 435.940 through § 435.965 of this subchapter), requires State agencies to have adequate safeguards to assure that—

(1) Information exchanged by the State agencies is made available only to the extent necessary to assist in the valid administrative needs of the program receiving the information, and information received under section 6103(l)(7) of the Internal Revenue Code is exchanged only with agencies authorized to receive that information under that section of the Code; and

(2) The information is adequately stored and processed so that it is protected against unauthorized disclosure for other purposes.

(d) Section 1943 of the Act and section 1413 of the Affordable Care Act.

[51 FR 7210, Feb. 28, 1986, as amended at 77 FR 17203, Mar. 23, 2012]

§ 431.301 State plan requirements.

A State plan must provide, under a State statute that imposes legal sanctions, safeguards meeting the requirements of this subpart that restrict the use or disclosure of information concerning applicants and beneficiaries to purposes directly connected with the administration of the plan.

§ 431.302 Purposes directly related to State plan administration.

Purposes directly related to plan administration include—

(a) Establishing eligibility;

(b) Determining the amount of medical assistance;

(c) Providing services for beneficiaries; and

(d) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the plan.

§ 431.303 State authority for safeguarding information.

The Medicaid agency must have authority to implement and enforce the provisions specified in this subpart for safeguarding information about applicants and beneficiaries.

§ 431.304 Publicizing safeguarding requirements.

(a) The agency must publicize provisions governing the confidential nature of information about applicants and

beneficiaries, including the legal sanctions imposed for improper disclosure and use.

(b) The agency must provide copies of these provisions to applicants and beneficiaries and to other persons and agencies to whom information is disclosed.

§ 431.305 Types of information to be safeguarded.

(a) The agency must have criteria that govern the types of information about applicants and beneficiaries that are safeguarded.

(b) This information must include at least—

(1) Names and addresses;

(2) Medical services provided;

(3) Social and economic conditions or circumstances;

(4) Agency evaluation of personal information;

(5) Medical data, including diagnosis and past history of disease or disability; and

(6) Any information received for verifying income eligibility and amount of medical assistance payments (see § 435.940 through § 435.965 of this subchapter). Income information received from SSA or the Internal Revenue Service must be safeguarded according to the requirements of the agency that furnished the data, including section 6103 of the Internal Revenue Code, as applicable.

(7) Any information received in connection with the identification of legally liable third party resources under § 433.138 of this chapter.

(8) Social Security Numbers.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987; 77 FR 17203, Mar. 23, 2012]

§ 431.306 Release of information.

(a) The agency must have criteria specifying the conditions for release and use of information about applicants and beneficiaries.

(b) Access to information concerning applicants or beneficiaries must be restricted to persons or agency representatives who are subject to standards of confidentiality that are comparable to those of the agency.

(c) The agency must not publish names of applicants or beneficiaries.

(d) The agency must obtain permission from a family or individual, whenever possible, before responding to a request for information from an outside source, unless the information is to be used to verify income, eligibility and the amount of medical assistance payment under section 1137 of this Act and §§ 435.940 through 435.965 of this chapter.

If, because of an emergency situation, time does not permit obtaining consent before release, the agency must notify the family or individual immediately after supplying the information.

(e) The agency's policies must apply to all requests for information from outside sources, including governmental bodies, the courts, or law enforcement officials.

(f) If a court issues a subpoena for a case record or for any agency representative to testify concerning an applicant or beneficiary, the agency must inform the court of the applicable statutory provisions, policies, and regulations restricting disclosure of information.

(g) Before requesting information from, or releasing information to, other agencies to verify income, eligibility and the amount of assistance under § 435.940 through § 435.965 of this subchapter, the agency must execute data exchange agreements with those agencies, as specified in § 435.945(i) of this subchapter.

(h) Before requesting information from, or releasing information to, other agencies to identify legally liable third party resources under § 433.138(d) of this chapter, the agency must execute data exchanges agreements, as specified in § 433.138(h)(2) of this chapter.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987; 77 FR 17203, Mar. 23, 2012]

§ 431.307 Distribution of information materials.

(a) All materials distributed to applicants, beneficiaries, or medical providers must—

(1) Directly relate to the administration of the Medicaid program;

(2) Have no political implications except to the extent required to implement the National Voter Registration

Act of 1993 (NVRA) Pub. L. 103–931; for States that are exempt from the requirements of NVRA, voter registration may be a voluntary activity so long as the provisions of section 7(a)(5) of NVRA are observed;

(3) Contain the names only of individuals directly connected with the administration of the plan; and

(4) Identify those individuals only in their official capacity with the State or local agency.

(b) The agency must not distribute materials such as ''holiday'' greetings, general public announcements, partisan voting information and alien registration notices.

(c) The agency may distribute materials directly related to the health and welfare of applicants and beneficiaries, such as announcements of free medical examinations, availability of surplus food, and consumer protection information.

(d) Under NVRA, the agency must distribute voter information and registration materials as specified in NVRA.

[44 FR 17934, Mar. 29, 1979, as amended at 61 FR 58143, Nov. 13, 1996]

Subpart G—Section 1115 Demonstrations

SOURCE: 77 FR 11696, Feb. 27, 2012, unless otherwise noted.

§ 431.400 Basis and purpose.

(a) *Basis.* This subpart implements provisions in section 1115(d) of the Act, which requires all of the following:

(1) The establishment of application requirements for Medicaid and CHIP demonstration projects that provide for:

(i) A process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedure Act, or requirements that are unreasonable or unnecessarily burdensome with respect to State compliance.

(ii) Requirements relating to all of the following:

(A) The goals of the program to be implemented or renewed under the demonstration project.

(B) Expected State and Federal costs and coverage projections of the State demonstration project.

(C) Specific plans of the State to ensure the demonstration project will be in compliance with titles XIX or XXI of the Act.

(2) A process for public notice and comment after a demonstration application is received by the Secretary that is sufficient to ensure a meaningful level of public input.

(3) A process for the submission of reports to the Secretary by a State relating to the implementation of a demonstration project.

(4) Periodic evaluation of demonstration projects by the Secretary.

(b) *Purpose.* This subpart sets forth a process for application and review of Medicaid and CHIP demonstration projects that provides for transparency and public participation.

§ 431.404 Definitions.

For the purposes of this subpart:

Demonstration means any experimental, pilot, or demonstration project which the Secretary approves under the authority of section 1115 of the Act because, in the judgment of the Secretary, it is likely to assist in promoting the statutory objectives of the Medicaid or CHIP program.

Indian Health Program means a program as defined at section 4(12) of the Indian Health Care Improvement Act, (Pub. L. 94–437).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action, consistent with the provisions of § 431.408 of this subpart.

§ 431.408 State public notice process.

(a) *General.* A State must provide at least a 30-day public notice and comment period regarding applications for a demonstration project, or an extension of an existing demonstration project that the State intends to submit to CMS for review and consideration.

(1) *Public notice and comment period.* Prior to submitting an application to

CMS for a new demonstration project or an extension of a previously approved demonstration project, the State must provide at least a 30-day public notice and comment period, and the public notice shall include all of the following information:

(i) A comprehensive description of the demonstration application or extension to be submitted to CMS that contains a sufficient level of detail to ensure meaningful input from the public, including:

(A) The program description, goals, and objectives to be implemented or extended under the demonstration project, including a description of the current or new beneficiaries who will be impacted by the demonstration.

(B) To the extent applicable, the proposed health care delivery system and the eligibility requirements, benefit coverage and cost sharing (premiums, co-payments, and deductibles) required of individuals that will be impacted by the demonstration, and how such provisions vary from the State's current program features.

(C) An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budgetary data, if applicable. This includes a financial analysis of any changes to the demonstration requested by the State in its extension request.

(D) The hypothesis and evaluation parameters of the demonstration.

(E) The specific waiver and expenditure authorities that the State believes to be necessary to authorize the demonstration.

(ii) The locations and Internet address where copies of the demonstration application are available for public review and comment.

(iii) Postal and Internet email addresses where written comments may be sent and reviewed by the public, and the minimum 30-day time period in which comments will be accepted.

(iv) The location, date, and time of at least two public hearings convened by the State to seek public input on the demonstration application.

(2) *Statement of public notice and public input procedures.* (i) The State shall publish its public notice process, public input process, planned hearings, the demonstration application(s), and a link to the relevant Medicaid demonstration page(s) on the CMS Web site in a prominent location on either the main page of the public Web site of the State agency responsible for making applications for demonstrations or on a demonstration-specific Web page that is linked in a readily identifiable way to the main page of the State agency's Web site. The State must maintain and keep current the public Web site throughout the entire public comment and review process.

(ii) The State shall also publish an abbreviated public notice which must include a summary description of the demonstration, the location and times of the two or more public hearings, and an active link to the full public notice document on the State's Web site in the State's administrative record in accordance with the State's Administrative Procedure Act, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to CMS or in the newspapers of widest circulation in each city with a population of 100,000, or more, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to CMS, or both.

(iii) The State must also utilize additional mechanisms, such as an electronic mailing list, to notify interested parties of the demonstration application(s).

(3) *Public hearings.* At least 20 days prior to submitting an application for a new demonstration project or extension of an existing demonstration project to CMS for review, the State must have conducted at least two public hearings, on separate dates and at separate locations, regarding the State's demonstration application at which members of the public throughout the State have an opportunity to provide comments. The State must use telephonic and/or Web conference capabilities for at least one of the two required public hearings to ensure statewide accessibility to the public hearing unless it can document it has afforded the public throughout the State the opportunity to provide comment, such as

holding the two public hearings in geographically distinct areas of the State. The State must use at least two of the following public forums:

(i) The Medical Care Advisory Committee that operates in accordance with §431.12 of this subpart; or

(ii) A commission or other similar process, where meetings are open to members of the public; or

(iii) A State legislative process, which would afford an interested party the opportunity to learn about the contents of the demonstration application, and to comment on its contents; or

(iv) Any other similar process for public input that would afford an interested party the opportunity to learn about the contents of the demonstration application, and to comment on its contents.

(b) *Tribal consultation and seeking advice from Indian health providers and urban Indian organizations.* A State with Federally-recognized Indian tribes, Indian health programs, and/or urban Indian health organizations shall include a process to consult with the Indian tribes, and seek advice from Indian Health programs and urban Indian health organizations in the State, prior to submission of an application to CMS for a new demonstration project, or an extension of a previously approved demonstration project, that has or would have a direct effect on Indians, tribes, on Indian health programs, or on urban Indian health organizations.

(1) For initial applications and applications extending existing demonstration projects that have a direct effect on Indians, tribes, Indian health programs, and urban Indian health organizations in the State, the State must demonstrate that it has conducted consultation activities with tribes and sought advice from Indian health programs and urban Indian health organizations prior to submission of such application.

(2) Consultation with Federally-recognized Indian tribes and solicitation of advice from affected Indian health providers and urban Indian organizations must be conducted in accordance with the consultation process outlined in the July 17, 2001 letter or the State's formal tribal consultation agreement or process and the process for seeking advice from Indian Health providers must be conducted as outlined in the State's approved Medicaid State Plan.

(3) Documentation of the State's consultation activities must be included in the demonstration application, which must describe the notification process, the entities involved in the consultation(s), the date(s) and location(s) of the consultation(s), issues raised, and the potential resolution for such issues.

§431.412 Application procedures.

(a) *Initial demonstration application content.* (1) Applications for initial approval of a demonstration will not be considered complete unless they comply with the public notice process set forth in §431.408(a) of this subpart, and include the following:

(i) A comprehensive program description of the demonstration, including the goals and objectives to be implemented under the demonstration project.

(ii) A description of the proposed health care delivery system, eligibility requirements, benefit coverage and cost sharing (premiums, copayments, and deductibles) required of individuals who will be impacted by the demonstration to the extent such provisions would vary from the State's current program features and the requirements of the Act.

(iii) An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budgetary data, if applicable.

(iv) Current enrollment data, if applicable, and enrollment projections expected over the term of the demonstration for each category of beneficiary whose health care coverage is impacted by the demonstration.

(v) Other program features that the demonstration would modify in the State's Medicaid and CHIP programs.

(vi) The specific waiver and expenditure authorities that the State believes to be necessary to authorize the demonstration.

(vii) The research hypotheses that are related to the demonstration's proposed changes, goals, and objectives, a plan for testing the hypotheses in the context of an evaluation, and, if a

quantitative evaluation design is feasible, the identification of appropriate evaluation indicators.

(viii) Written documentation of the State's compliance with the public notice requirements set forth in § 431.408 of this subpart, with a report of the issues raised by the public during the comment period, which shall be no less than 30 days, and how the State considered those comments when developing the demonstration application.

(2) CMS may request, or the State may propose application modifications, as well as additional information to aid in the review of the application. If an application modification substantially changes the original demonstration design, CMS may, at its discretion, direct an additional 30-day public comment period.

(3) This section does not preclude a State from submitting to CMS a preapplication concept paper or from conferring with CMS about its intent to seek a demonstration prior to submitting a completed application.

(b) *Demonstration application procedures.* A State application for approval of a new demonstration project or an extension of an existing demonstration project must be submitted to CMS as both printed and electronic documents. Electronic documents must be submitted in a format that will be accessible to individuals with disabilities.

(1) Consistent with § 431.416(a) of this subpart, within 15 days of receipt of a complete application, CMS will send the State a written notice informing the State of receipt of the submitted application, the date in which the Secretary received the State's demonstration application and the start date of the 30-day Federal public notice process set forth in § 431.416 of this subpart. The written notice—

(i) Is provided for purposes of initiating the Federal-level public comment period and does not preclude a determination that, based on further review, further information is required to supplement or support the application, or that the application cannot be approved because a required element is missing or insufficient.

(ii) Does not prevent a State from modifying its application or submitting any supplementary information it determines necessary to support CMS' review of its application.

(2) Within 15 days of receipt of a demonstration application that CMS determines is incomplete, CMS will send the State a written notice of the elements missing from the application.

(3) CMS will publish on its Web site at regular intervals the status of all State submissions, including information received from the State while the State works with CMS to meet the demonstration application process set forth in this section.

(c) *Demonstration extension request.* A request to extend an existing demonstration under sections 1115(a), (e), and (f) of the Act will be considered only if it is submitted at least 12 months prior to the expiration date of the demonstration when requesting an extension under section 1115(e) of the Act or 6 months prior to the expiration date of the demonstration when requesting an extension under section 1115(a) or (f) of the Act, unless a longer time frame is specified in the Special Terms and Conditions for the original demonstration. An extension application, including an extension for the purpose of phasing out a demonstration, must be sent from the Governor of the State to the Secretary.

(1) *Changes to existing demonstration.* If an extension application includes substantial changes to the existing demonstration, CMS may, at its discretion, treat the application as an application for a new demonstration.

(2) *Demonstration extension application.* An application to extend an existing demonstration will be considered complete, for purposes of initiating the Federal-level public notice period, when the State provides the following:

(i) A historical narrative summary of the demonstration project, which includes the objectives set forth at the time the demonstration was approved, evidence of how these objectives have or have not been met, and the future goals of the program.

(ii) If changes are requested, a narrative of the changes being requested along with the objective of the change and the desired outcomes.

(iii) A list and programmatic description of the waivers and expenditure authorities that are being requested for

the extension period, or a statement that the State is requesting the same waiver and expenditure authorities as those approved in the current demonstration.

(iv) Summaries of External Quality Review Organization (EQRO) reports, managed care organization (MCO) and State quality assurance monitoring, and any other documentation of the quality of and access to care provided under the demonstration, such as the CMS Form 416 EPSDT/CHIP report.

(v) Financial data demonstrating the State's historical and projected expenditures for the requested period of the extension, as well as cumulatively over the lifetime of the demonstration. This includes a financial analysis of changes to the demonstration requested by the State.

(vi) An evaluation report of the demonstration, inclusive of evaluation activities and findings to date, plans for evaluation activities during the extension period, and if changes are requested, identification of research hypotheses related to the changes and an evaluation design for addressing the proposed revisions.

(vii) Documentation of the State's compliance with the public notice process set forth in §431.408 of this subpart, including the post-award public input process described in §431.420(c) of this subpart, with a report of the issues raised by the public during the comment period and how the State considered the comments when developing the demonstration extension application.

(3) CMS may request, or the State may propose application modifications, as well as additional information to aid in the review of an application to extend a demonstration. If an application modification substantially changes the original demonstration design, CMS may, at its discretion, direct an additional 30-day public comment period.

(4) Upon application from the State, the Secretary may extend existing demonstration projects on a temporary basis for the period during which a successor demonstration is under review, without regard to the date when the application was submitted.

(d) *Approvals.* Approval of a new demonstration or a demonstration extension will generally be prospective only and Federal Financial Participation (FFP) will not be available for changes to the demonstration that have not been approved by CMS.

§431.416 Federal public notice and approval process.

(a) *General.* Within 15 days of receipt of a complete application from the State for a new demonstration project or an extension of a previously approved demonstration project, CMS will:

(1) Send the State a written notice informing the State of receipt of the demonstration application, the date in which the Secretary received the State's demonstration application, the start dates of the 30-day Federal public notice process, and the end date of the 45-day minimum Federal decision-making period.

(2) Publish the written notice acknowledging receipt of the State's completed application on its Web site within the same 15-day timeframe.

(b) *Public comment period.* Upon notifying a State of a completed application, CMS will solicit public comment regarding such demonstration application for 30 days by doing the following:

(1) Publishing the following on the CMS Web site:

(i) The written notice of CMS receipt of the State's complete demonstration application.

(ii) Demonstration applications, including supporting information submitted by the State as part of the complete application, and associated concept papers, as applicable.

(iii) The proposed effective date of the demonstration.

(iv) Addresses to which inquiries and comments from the public may be directed to CMS by mail or email.

(2) Notifying interested parties through a mechanism, such an electronic mailing list, that CMS will create for this purpose.

(c) *Public disclosure.* CMS will publish on its Web site, at regular intervals, appropriate information, which may include, but is not limited to the following:

(1) Relevant status update(s);

(2) A listing of the issues raised through the public notice process.

(d) *Publishing of comments.* (1) CMS will publish written comments electronically through its Web site or an alternative Web site.

(2) CMS will review and consider all comments received by the deadline, but will not provide written responses to public comments. While comments may be submitted after the deadline, CMS cannot assure that these comments will be considered.

(e) *Approval of a demonstration application.* (1) CMS will not render a final decision on a demonstration application until at least 45 days after notice of receipt of a completed application, to receive and consider public comments.

(2) CMS may expedite this process under the exception to the normal public notice process provisions in § 431.416(g) of this subpart.

(f) *Administrative record.* (1) CMS will maintain, and publish on its public Web site, an administrative record that may include, but is not limited to the following:

(i) The demonstration application from the State.

(ii) The State's disaster exemption request and CMS' response, if applicable.

(iii) Written public comments sent to the CMS and any CMS responses.

(iv) If an application is approved, the final special terms and conditions, waivers, expenditure authorities, and award letter sent to the State.

(v) If an application is denied, the disapproval letter sent to the State.

(vi) The State acceptance letter, as applicable.

(vii) Specific requirements related to the approved and agreed upon terms and conditions, such as implementation reviews, evaluation design, quarterly progress reports, annual reports, and interim and/or final evaluation reports.

(viii) Notice of the demonstration's suspension or termination, if applicable.

(2) To ensure that the public has access to all documentation related to the demonstration project, including the aforementioned items, we will also provide a link to the State's public Web site.

(g) *Exemption from the normal public notice process.* (1) CMS may waive, in whole or in part, the Federal and State public notice procedures to expedite a decision on a proposed demonstration or demonstration extension request that addresses a natural disaster, public health emergency, or other sudden emergency threats to human lives.

(2) The Secretary may exempt a State from the normal public notice process or the required time constraints imposed in this section or § 431.408(a) of this subpart when the State demonstrates to CMS the existence of unforeseen circumstances resulting from a natural disaster, public health emergency, or other sudden emergency that directly threatens human lives that warrant an exception to the normal public notice process.

(i) The State is expected to discharge its basic responsibilities in submitting demonstration applications to the Secretary as required in § 431.412 of this subpart.

(ii) Such applications will be posted on the CMS Web site.

(3) A State must establish (or meet) all of the following criteria to obtain such an exemption from the normal public notice process requirements:

(i) The State acted in good faith, and in a diligent, timely, and prudent manner.

(ii) The circumstances constitute an emergency and could not have been reasonably foreseen.

(iii) Delay would undermine or compromise the purpose of the demonstration and be contrary to the interests of beneficiaries.

(4) CMS will publish on its Web site any disaster exemption determinations within 15 days of approval, as well as the revised timeline for public comment or post-award processes, if applicable.

§ 431.420 Monitoring and compliance.

(a) *General.* (1) Any provision of the Social Security Act that is not expressly waived by CMS in its approval of the demonstration project are not waived, and States may not stop compliance with any of these provisions not expressly waived. Waivers may be limited in scope to the extent necessary to achieve a particular purpose

or to the extent of a particular regulatory requirement implementing the statutory provision.

(2) States must comply with the terms and conditions of the agreement between the Secretary and the State to implement a State demonstration project.

(b) *Implementation reviews.* (1) The terms and conditions will provide that the State will perform periodic reviews of the implementation of the demonstration.

(2) CMS will review documented complaints that a State is failing to comply with requirements specified in the special terms and conditions and implementing waivers of any approved demonstration.

(3) CMS will promptly share with the State complaints that CMS has received and will also provide notification of any applicable monitoring and compliance issues.

(c) *Post award.* Within 6 months after the implementation date of the demonstration and annually thereafter, the State must hold a public forum—

(1) To solicit comments on the progress of a demonstration project.

(2) At which members of the public have an opportunity to provide comments and in such time as to include a summary of the forum in the quarterly report associated with the quarter in which the forum was held, as well as in its annual report to CMS.

(3) The public forum to solicit feedback on the progress of a demonstration project must occur using one of the following:

(i) A Medical Care Advisory Committee that operates in accordance with § 431.412 of this subpart.

(ii) A commission or other similar process, where meetings are open to members of the public, and would afford an interested party the opportunity to learn about the demonstration's progress.

(iii) The State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

(4) [Reserved]

(d) *Terminations and suspensions.* (1) The Secretary may suspend or terminate a demonstration in whole or in part, any time before the date of expiration, whenever it determines that the State has materially failed to comply with the terms of the demonstration project.

(2) The Secretary may also withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes.

(3) The terms and conditions for the demonstration will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.

(e) *Closeout costs.* When a demonstration is terminated, suspended, or if waivers or expenditure authority are withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination of the demonstration or expenditure authority, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) The State must fully cooperate with CMS or an independent evaluator selected by CMS to undertake an independent evaluation of any component of the demonstration.

(2) The State must submit all requested data and information to CMS or the independent evaluator.

§ 431.424 Evaluation requirements.

(a) *General.* States are permitted and encouraged to use a range of appropriate evaluation strategies (including experimental and other quantitative and qualitative designs) in the application of evaluation techniques with the approval of CMS.

(b) *Demonstration evaluations.* Demonstration evaluations will include the following:

(1) *Quantitative research methods.* (i) These methods involve the empirical investigation of the impact of key programmatic features of the demonstration.

(ii) CMS will consider alternative evaluation designs when quantitative designs are technically infeasible or not well suited to the change made by the demonstration.

(2) *Approaches that minimize beneficiary impact.* The evaluation process must minimize burden on beneficiaries and protect their privacy in terms of implementing and operating the policy approach to be demonstrated while ensuring the impact of the demonstration is measured.

(c) *Evaluation design plan.* (1) The State will submit and receive CMS approval of a design for an evaluation of the demonstration project and publish this document to the State's public Web site within 30 days of CMS approval.

(2) The draft demonstration evaluation design must include all of the following:

(i) A discussion of the demonstration hypotheses that are being tested including monitoring and reporting on the progress towards the expected outcomes.

(ii) The data that will be utilized and the baseline value for each measure.

(iii) The methods of data collection.

(iv) A description of how the effects of the demonstration will be isolated from those other changes occurring in the State at the same time through the use of comparison or control groups to identify the impact of significant aspects of the demonstration.

(v) A proposed date by which a final report on findings from evaluation activities conducted under the evaluation plan must be submitted to CMS.

(vi) Any other information pertinent to the State's research on the policy operations of the demonstration operations.

(d) *Evaluations for demonstration extensions.* (1) In the event that the State requests to extend the demonstration beyond the current approval period under the authority of section 1115(a), (e), or (f) of the Act, the State must submit an interim evaluation report as part of the State's request for a subsequent renewal of the demonstration.

(2) State evaluations must be published on the State's public Web site within 30 days of submission to CMS.

(e) *Approved evaluation designs.* The State must publish the CMS-approved demonstration evaluation design on the State's public Web site within 30 days of CMS approval.

(f) *Federal evaluations.* The State must comply with all requirements set forth in this subpart.

(g) *Federal public notice.* CMS will post, or provide a link to the State's public Web site, all evaluation materials, including research and data collection, on its Web site for purposes of sharing findings with the public within 30 days of receipt of materials.

§ 431.428 Reporting requirements.

(a) *Annual reports.* The State must submit an annual report to CMS documenting all of the following:

(1) Any policy or administrative difficulties in the operation of the demonstration.

(2) The status of the health care delivery system under the demonstration with respect to issues and/or complaints identified by beneficiaries.

(3) The impact of the demonstration in providing insurance coverage to beneficiaries and uninsured populations.

(4) Outcomes of care, quality of care, cost of care and access to care for demonstration populations.

(5) The results of beneficiary satisfaction surveys, if conducted during the reporting year, grievances and appeals.

(6) The existence or results of any audits, investigations or lawsuits that impact the demonstration.

(7) The financial performance of the demonstration.

(8) The status of the evaluation and information regarding progress in achieving demonstration evaluation criteria.

(9) Any State legislative developments that may impact the demonstration.

(10) The results/impact of any demonstration programmatic area defined by CMS that is unique to the demonstration design or evaluation hypothesis.

(11) A summary of the annual post-award public forum, including all public comments received regarding the progress of the demonstration project.

(b) *Submitting and publishing annual reports.* States must submit a draft annual report to CMS no later than 90

days after the end of each demonstration year, or as specified in the demonstration's STCs. The State must publish its draft annual report on its public Web site within 30 days of submission to CMS.

(1) Within 60 days of receipt of comments from CMS, the State must submit to CMS the final annual report for the demonstration year.

(2) The final annual report is to be published on the State's public Web site within 30 days of approval by CMS.

Subparts H–L [Reserved]

Subpart M—Relations With Other Agencies

§ 431.610 Relations with standard-setting and survey agencies.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(9) of the Act, concerning the designation of State authorities to be responsible for establishing and maintaining health and other standards for institutions participating in Medicaid; and

(2) Section 1902(a)(33) of the Act, concerning the designation of the State licensing agency to be responsible for determining whether institutions and agencies meet requirements for participation in the State's Medicaid program.

(3) Section 1919(g)(1)(A) of the Act, concerning responsibilities of the State for certifying the compliance of non-State operated NFs with requirements of participation in the State's Medicaid program.

(b) *Designated agency responsible for health standards.* A State plan must designate, as the State authority responsible for establishing and maintaining health standards for private or public institutions that provide services to Medicaid beneficiaries, the same State agency that is used by the Secretary to determine qualifications of institutions and suppliers of services to participate in Medicare (see 42 CFR 405.1902). The requirement for establishing and maintaining standards does not apply with respect to religious nonmedical institutions as defined in § 440.170(b) of this chapter.

(c) *Designated agency responsible for standards other than health standards.* The plan must designate the Medicaid agency or other appropriate State authority or authorities to be responsible for establishing and maintaining standards, other than those relating to health, for private or public institutions that provide services to Medicaid beneficiaries.

(d) *Description and retention of standards.* (1) The plan must describe the standards established under paragraphs (b) and (c) of this section.

(2) The plan must provide that the Medicaid agency keeps these standards on file and makes them available to the Administrator upon request.

(e) *Designation of survey agency.* The plan must provide that—

(1) The agency designated in paragraph (b) of this section, or another State agency responsible for licensing health institutions in the State, determines for the Medicaid agency whether institutions and agencies meet the requirements for participation in the Medicaid program; and

(2) The agency staff making the determination under paragraph (e)(1) of this section is the same staff responsible for making similar determinations for institutions or agencies participating under Medicare; and

(3) The agency designated in paragraph (e)(1) of this section makes recommendations regarding the effective dates of provider agreements, as determined under § 431.108.

(f) *Written agreement required.* The plan must provide for a written agreement (or formal written intra-agency arrangement) between the Medicaid agency and the survey agency designated under paragraph (e) of this section, covering the activities of the survey agency in carrying out its responsibilities. The agreement must specify that—

(1) Federal requirements and the forms, methods and procedures that the Administrator designates will be used to determine provider eligibility and certification under Medicaid;

(2) Inspectors surveying the premises of a provider will—

(i) Complete inspection reports;

(ii) Note on completed reports whether or not each requirement for which an inspection is made is satisfied; and

(iii) Document deficiencies in reports;

(3) The survey agency will keep on file all information and reports used in determining whether participating facilities meet Federal requirements; and

(4) The survey agency will make the information and reports required under paragraph (f)(3) of this section readily accessible to HHS and the Medicaid agency as necessary—

(i) For meeting other requirements under the plan; and

(ii) For purposes consistent with the Medicaid agency's effective administration of the program.

(g) *Responsibilities of survey agency.* The plan must provide that, in certifying NFs, HHAs, and ICF–IIDs, the survey agency designated under paragraph (e) of this section will —

(1) Review and evaluate medical and independent professional review team reports obtained under part 456 of this subchapter as they relate to health and safety requirements;

(2) Have qualified personnel perform on-site inspections periodically as appropriate based on the timeframes in the correction plan and—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For non-State operated NFs, within the timeframes specified in § 488.308 of this chapter.

(3) Have qualified personnel perform on-site inspections—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For intermediate care facilities with deficiencies as described in §§ 442.112 and 442.113 of this subchapter, within 6 months after initial correction plan approval and every 6 months thereafter as required under those sections.

(h) *FFP for survey responsibilities.* (1) FFP is available in expenditures that the survey agency makes to carry out its survey and certification responsibilities under the agreement specified in paragraph (f) of this section.

(2) FFP is not available in any expenditures that the survey agency makes that are attributable to the State's overall responsibilities under State law and regulations for establishing and maintaining standards.

[43 FR 45188, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980; 53 FR 20494, June 3, 1988; 57 FR 43923, Sept. 23, 1992; 59 FR 56233, Nov. 10, 1994; 62 FR 43936, Aug. 18, 1997; 64 FR 67052, Nov. 30, 1999; 78 FR 72320, Dec. 2, 2013]

§ 431.615 Relations with State health and vocational rehabilitation agencies and title V grantees.

(a) *Basis and purpose.* This section implements section 1902(a)(11) and (22)(C) of the Act, by setting forth State plan requirements for arrangements and agreements between the Medicaid agency and—

(1) State health agencies;

(2) State vocational rehabilitation agencies; and

(3) Grantees under title V of the Act, Maternal and Child Health and Crippled Children's Services.

(b) *Definitions.* For purposes of this section—

''Title V grantee'' means the agency, institution, or organization receiving Federal payments for part or all of the cost of any service program or project authorized by title V of the Act, including—

(1) Maternal and child health services;

(2) Crippled children's services;

(3) Maternal and infant care projects;

(4) Children and youth projects; and

(5) Projects for the dental health of children.

(c) *State plan requirements.* A state plan must—

(1) Describe cooperative arrangements with the State agencies that administer, or supervise the administration of, health services and vocational rehabilitation services designed to make maximum use of these services;

(2) Provide for arrangements with title V grantees, under which the Medicaid agency will utilize the grantee to furnish services that are included in the State plan;

(3) Provide that all arrangements under this section meet the requirements of paragraph (d) of this section; and

(4) Provide, if requested by the title V grantee in accordance with the arrangements made under this section, that the Medicaid agency reimburse the grantee or the provider for the cost of services furnished beneficiaries by or through the grantee.

(d) *Content of arrangements.* The arrangements referred to in paragraph (c) must specify, as appropriate—

(1) The mutual objectives and responsibilities or each party to the arrangement;

(2) The services each party offers and in what circumstances;

(3) The cooperative and collaborative relationships at the State level;

(4) The kinds of services to be provided by local agencies; and

(5) Methods for—

(i) Early identification of individuals under 21 in need of medical or remedial services;

(ii) Reciprocal referrals;

(iii) Coordinating plans for health services provided or arranged for beneficiaries;

(iv) Payment or reimbursement;

(v) Exchange of reports of services furnished to beneficiaries;

(vi) Periodic review and joint planning for changes in the agreements;

(vii) Continuous liaison between the parties, including designation of State and local liaison staff; and

(viii) Joint evaluation of policies that affect the cooperative work of the parties.

(e) *Federal financial participation.* FFP is available in expenditures for Medicaid services provided to beneficiaries through an arrangement under this section.

§ 431.620 Agreement with State mental health authority or mental institutions.

(a) *Basis and purpose.* This section implements section 1902(a)(20)(A) of the Act, for States offering Medicaid services in institutions for mental diseases for beneficiaries aged 65 or older, by specifying the terms of the agreement those States must have with other State authorities and institutions. (See part 441, subpart C of this chapter for regulations implementing section 1902(a)(20) (B) and (C).)

(b) *Definition.* For purposes of this section, an ''institution for mental diseases'' means an institution primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases. This includes medical attention, nursing care, and related services.

(c) *State plan requirement.* A State plan that includes Medicaid for persons aged 65 or older in institutions for mental diseases must provide that the Medicaid agency has in effect a written agreement with—

(1) The State authority or authorities concerned with mental diseases; and

(2) Any institution for mental diseases that is not under the jurisdiction of those State authorities, and that provides services under Medicaid to beneficiaries aged 65 or older.

(d) *Provisions required in an agreement.* The agreement must specify the respective responsibilities of the agency and the authority or institution, including arrangements for—

(1) Joint planning between the parties to the agreement;

(2) Development of alternative methods of care;

(3) Immediate readmission to an institution when needed by a beneficiary who is in alternative care;

(4) Access by the agency to the institution, the beneficiary, and the beneficiary's records when necessary to carry out the agency's responsibilities;

(5) Recording, reporting, and exchanging medical and social information about beneficiaries; and

(6) Other procedures needed to carry out the agreement.

[44 FR 17935, Mar. 23, 1979]

§ 431.621 State requirements with respect to nursing facilities.

(a) *Basis and purpose.* This section implements sections 1919(b)(3)(F) and 1919(e)(7) of the Act by specifying the terms of the agreement the State must have with the State mental health and Intellectual Disability authorities concerning the operation of the State's preadmission screening and annual resident review (PASARR) program.

(b) *State plan requirement.* The State plan must provide that the Medicaid agency has in effect a written agreement with the State mental health and

Intellectual Disability authorities that meets the requirements specified in paragraph (c) of this section.

(c) *Provisions required in an agreement.* The agreement must specify the respective responsibilities of the agency and the State mental health and Intellectual Disability authorities, including arrangements for—(1) Joint planning between the parties to the agreement;

(2) Access by the agency to the State mental health and Intellectual Disability authorities' records when necessary to carry out the agency's responsibilities;

(3) Recording, reporting, and exchanging medical and social information about individuals subject to PASARR;

(4) Ensuring that preadmission screenings and annual resident reviews are performed timely in accordance with §§ 483.112(c) and 483.114(c) of this part;

(5) Ensuring that, if the State mental health and Intellectual Disability authorities delegate their respective responsibilities, these delegations comply with § 483.106(e) of this part;

(6) Ensuring that PASARR determinations made by the State mental health and Intellectual Disability authorities are not countermanded by the State Medicaid agency, except through the appeals process, but that the State mental health and Intellectual Disability authorities do not use criteria which are inconsistent with those adopted by the State Medicaid agency under its approved State plan;

(7) Designating the independent person or entity who performs the PASARR evaluations for individuals with MI; and

(8) Ensuring that all requirements of §§ 483.100 through 483.136 are met.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 431.625 Coordination of Medicaid with Medicare part B.

(a) *Basis and purpose.* (1) Section 1843(a) of the Act requires the Secretary to have entered into an agreement with any State that requested that agreement before January 1, 1970, or during calendar year 1981, under which the State could enroll certain Medicare-eligible beneficiaries under Medicare Part B and agree to pay their premiums.

(2) Section 1902(a)(10) of the Act (in clause (II) following subparagraph (D)), allows the State to pay the premium, deductibles, cost sharing, and other charges for beneficiaries enrolled under Medicare Part B without obligating itself to provide the range of Part B benefits to other beneficiaries; and

(3) Section 1903 (a)(1) and (b) of the Act authorizes FFP for State payment of Medicare Part B premiums for certain beneficiaries.

(4) This section—

(i) Specifies the exception, relating to Part B coverage, from the requirement to provide comparable services to all beneficiaries; and

(ii) Prescribes FFP rules concerning State payment for Medicare premiums and for services that could have been covered under Medicare.

(5) Section 1902(a)(15) of the Act requires that if a State chooses to pay only a portion of deductibles, cost sharing or other charges for beneficiaries enrolled under Medicare Part B, the portion that is to be paid by a Medicaid beneficiary must be reasonably related to the beneficiary's income and resources.

(b) *Exception from obligation to provide comparable services; State plan requirement.* (1) The State's payment of premiums, deductibles, cost sharing, or similar charges under Part B does not obligate it to provide the full range of Part B services to beneficiaries not covered by Medicare.

(2) The State plan must specify this exception if it applies.

(c) *Effect of payment of premiums on State liability for cost sharing.* (1) State payment of Part B premiums on behalf of a Medicaid beneficiary does not obligate it to pay on the beneficiary's behalf the Part B deductible and coinsurance amounts for those Medicare Part B services not covered in the Medicaid State plan.

(2) If a State pays on a beneficiary's behalf any portion of the deductible or cost sharing amounts under Medicare Part B, the portion paid by a State must be reasonably related to the beneficiary's income and resources.

(d) *Federal financial participation: Medicare Part B premiums*—(1) *Basic rule*. Except as provided in paragraph (d)(2) of this section, FFP is not available in State expenditures for Medicare Part B premiums for Medicaid beneficiaries unless the beneficiaries receive money payments under title I, IV-A, X, XIV, XVI (AABD or SSI) of the Act, or State supplements as permitted under section 1616(a) of the Act, or as required by section 212 of Pub. L. 93–66.

(2) *Exception*. FFP is available in expenditures for Medicare Part B premiums for the following groups:

(i) AFDC families required to be covered under §§435.112 and 436.116 of this subchapter, those eligible for continued Medicaid coverage despite increased income from employment;

(ii) Beneficiaries required to be covered under §§435.114, 435.134, and 436.112 of this subchapter, those eligible for continued Medicaid coverage despite increased income from monthly insurance benefits under title II of the Act;

(iii) Beneficiaries required to be covered under §435.135 of this subchapter, those eligible for continued Medicaid coverage despite increased income from cost-of-living increases under title II of the Act;

(iv) Beneficiaries of foster care maintenance payments or adoption assistance payments who, under Part E of title IV of the Act are considered as receiving AFDC;

(v) Individuals required to be covered under §435.120 of this chapter, that is, blind or disabled individuals who, under section 1619(b) of the Act, are considered to be receiving SSI;

(vi) Individuals who, in accordance with §§435.115 and 436.114 of this chapter are, for purposes of Medicaid eligibility, considered to be receiving AFDC. These are participants in a work supplementation program, or individuals denied AFDC because the payment would be less than $10;

(vii) Certain beneficiaries of Veterans Administration pensions during the limited time they are, under section 310(b) of Pub. L. 96–272, considered as receiving SSI, mandatory State supplements, or AFDC;

(viii) Disabled children living at home to whom the State provides Medicaid under section 1902(e)(3) of the Act;

(ix) Individuals who become ineligible for AFDC because of the collection or increased collection of child or spousal support, but, in accordance with section 406(h) of the Act, remain eligible for Medicaid for four more months; and

(x) Individuals who become ineligible for AFDC because they are no longer eligible for the disregard of earnings of $30 or of $30 plus one-third of the remainder, but, in accordance with section 402(a)(37) of the Act, are considered as receiving AFDC for a period of 9 to 15 months.

(3) No FFP is available in State Medicaid expenditures that could have been paid for under Medicare Part B but were not because the person was not enrolled in Part B. This limit applies to all beneficiaries eligible for enrollment under Part B, whether individually or through an agreement under section 1843(a) of the Act. However, FFP is available in expenditures required by §§435.914 and 436.901 of this subchapter for retroactive coverage of beneficiaries.

[43 FR 45188, Sept. 29, 1978, as amended at 44 FR 17935, Mar. 23, 1979; 52 FR 47933, Dec. 17, 1987; 53 FR 657, Jan. 11, 1988]

§431.630 Coordination of Medicaid with QIOs.

(a) The State plan may provide for the review of Medicaid services through a contract with a QIO designated under part 462 of this chapter. Medicaid requirements for medical and utilization review are deemed to be met for those services or providers subject to review under the contract.

(b) The State plan must provide that the contract with the QIO—

(1) Meets the requirements of §434.6(a) of this part;

(2) Includes a monitoring and evaluation plan by which the State ensures satisfactory performance by the QIO;

(3) Identifies the services and providers subject to QIO review;

(4) Ensures that the review activities performed by the QIO are not inconsistent with QIO review activities of

Medicare services and includes a description of whether and to what extent QIO determinations will be considered conclusive for Medicaid payment purposes.

[50 FR 15327, Apr. 17, 1985]

§ 431.635 Coordination of Medicaid with Special Supplemental Food Program for Women, Infants, and Children (WIC).

(a) *Basis.* This section implements sections 1902(a)(11)(C) and 1902(a) (53) of the Act, which provide for coordination of Medicaid with the Special Supplemental Food Program for Women, Infants, and Children (WIC) under section 17 of the Child Nutrition Act of 1966.

(b) *Definitions.* As used in this section, the terms *breastfeeding women*, *postpartum women*, and *pregnant women* mean women as defined in section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786(b)).

(c) *State plan requirements.* A State Plan must provide for—

(1) Coordinating operation of the Medicaid program with the State's operation of the Special Supplemental Food Program for Women, Infants, and Children;

(2) Providing timely written notice of the availability of WIC benefits to all individuals in the State who are determined to be eligible (including presumptively eligible) for Medicaid and who are:

(i) Pregnant women;

(ii) Postpartum women;

(iii) Breastfeeding women; and

(iv) Children under the age of 5.

(3) Referring individuals described under paragraphs (c)(2) (i) through (iv) of this section to the local agency responsible for administering the WIC program.

(d) *Notification requirements.* (1) The agency must give the written notice required under paragraph (c) of this section as soon as the agency identifies the individual (e.g., at the time of an eligibility determination for Medicaid) or immediately thereafter (e.g., at the time of notice of eligibility).

(2) The agency, no less frequently than annually, must also provide written notice of the availability of WIC benefits, including the location and telephone number of the local WIC agency or instructions for obtaining further information about the WIC program, to all Medicaid beneficiaries (including those found to be presumptively eligible) who are under age 5 or who are women who might be pregnant, postpartum, or breastfeeding as described in paragraphs (c)(2) (i) through (iv) of this section.

(3) The agency must effectively inform those individuals who are blind or deaf or who cannot read or understand the English language.

[57 FR 28103, June 24, 1992]

Subpart N—State Programs for Licensing Nursing Home Administrators

§ 431.700 Basis and purpose.

This subpart implements sections 1903(a)(29) and 1908 of the Act which require that the State plan include a State program for licensing nursing home administrators.

§ 431.701 Definitions.

Unless otherwise indicated, the following definitions apply for purposes of this subpart:

Agency means the State agency responsible for licensing individual practitioners under the State's healing arts licensing act.

Board means an appointed State board established to carry out a State program for licensing administrators of nursing homes, in a State that does not have a healing arts licensing act or an agency as defined in this section.

Licensed means certified by a State agency or board as meeting all of the requirements for a licensed nursing home administrator specified in this subpart.

Nursing home means any institution, facility, or distinct part of a hospital that is licensed or formally recognized as meeting nursing home standards established under State law, or that is determined under § 431.704 to be included under the requirements of this subpart. The term does not include—

(a) A religious nonmedical institution as defined in § 440.170(b) of this chapter; or

(b) A distinct part of a hospital, if the hospital meets the definition in

§ 440.10 or § 440.140 of this subchapter, and the distinct part is not licensed separately or formally approved as a nursing home by the State even though it is designated or certified as a skilled nursing facility.

Nursing home administrator means any person who is in charge of the general administration of a nursing home whether or not the person—

(a) Has an ownership interest in the home; or

(b) Shares his functions and duties with one or more other persons.

[43 FR 45188, Sept. 29, 1978, as amended at 64 FR 67052, Nov. 30, 1999]

§ 431.702 State plan requirement.

A State plan must provide that the State has a program for licensing administrators of nursing homes that meets the requirements of §§ 431.703 through 431.713 of this subpart.

§ 431.703 Licensing requirement.

The State licensing program must provide that only nursing homes supervised by an administrator licensed in accordance with the requirements of this subpart may operate in the State.

§ 431.704 Nursing homes designated by other terms.

If a State licensing law does not use the term ''nursing home,'' the CMS Administrator will determine the term or terms equivalent to ''nursing home'' for purposes of applying the requirements of this subpart. To obtain this determination, the Medicaid agency must submit to the Regional Medicaid Director copies of current State laws that define institutional health care facilities for licensing purposes.

§ 431.705 Licensing authority.

(a) The State licensing program must provide for licensing of nursing home administrators by—

(1) The agency designated under the healing arts act of the State; or

(2) A State licensing board.

(b) The State agency or board must perform the functions and duties specified in §§ 431.707 through 431.713 and the board must meet the membership requirements specified in § 431.706 of this subpart.

§ 431.706 Composition of licensing board.

(a) The board must be composed of persons representing professions and institutions concerned with the care and treatment of chronically ill or infirm elderly patients. However—

(1) A majority of the board members may not be representative of a single profession or category of institution; and

(2) Members not representative of institutions may not have a direct financial interest in any nursing home.

(b) For purposes of this section, nursing home administrators are considered representatives of institutions.

§ 431.707 Standards.

(a) The agency or board must develop, impose, and enforce standards that must be met by individuals in order to be licensed as a nursing home administrator.

(b) The standards must be designed to insure that nursing home administrators are—

(1) Of good character;

(2) Otherwise suitable; and

(3) Qualified to serve because of training or experience in institutional administration.

§ 431.708 Procedures for applying standards.

The agency or board must develop and apply appropriate procedures and techniques, including examinations and investigations, for determining if a person meets the licensing standards.

§ 431.709 Issuance and revocation of license.

Except as provided in § 431.714 of this subpart, the agency or board must—

(a) Issue licenses to persons who meet the agency's or board's standards; and

(b) Revoke or suspend a license if the agency or board determines that the person holding the license substantially fails to meet the standards.

§ 431.710 Provisional licenses.

To fill a position of nursing home administrator that unexpectedly becomes vacant, the agency or board may issue

one provisional license, for a single period not to exceed 6 months. The license may be issued to a person who does not meet all of the licensing requirements established under § 431.707 but who—

(a) Is of good character and otherwise suitable; and

(b) Meets any other standards established for provisional licensure by the agency or board.

§ 431.711 Compliance with standards.

The agency or board must establish and carry out procedures to insure that licensed administrators comply with the standards in this subpart when they serve as nursing home administrators.

§ 431.712 Failure to comply with standards.

The agency or board must investigate and act on all complaints it receives of violations of standards.

§ 431.713 Continuing study and investigation.

The agency or board must conduct a continuing study of nursing homes and administrators within the State to improve—

(a) Licensing standards; and

(b) The procedures and methods for enforcing the standards.

§ 431.714 Waivers.

The agency or board may waive any standards developed under § 431.707 of this subpart for any person who has served in the capacity of a nursing home administrator during all of the 3 calendar years immediately preceding the calendar year in which the State first meets the requirements in this subpart.

§ 431.715 Federal financial participation.

No FFP is available in expenditures by the licensing board for establishing and maintaining standards for the licensing of nursing home administrators.

Subpart O [Reserved]

Subpart P—Quality Control

GENERAL PROVISIONS

SOURCE: Sections 431.800 through 431.808 appear at 55 FR 22166, May 31, 1990, unless otherwise noted.

§ 431.800 Scope of subpart.

This subpart—

(a) Establishes State plan requirements for a Medicaid eligibility quality control (MEQC) program designed to reduce erroneous expenditures by monitoring eligibility determinations and a claims processing assessment system that monitors claims processing operations.

(b) Establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous Medicaid payments due to eligibility and beneficiary liability errors as detected through the MEQC program.

§ 431.802 Basis.

This subpart implements the following sections of the Act, which establish requirements for State plans and for payment of Federal financial participation (FFP) to States:

1902(a)(4) Administrative methods for proper and efficient operation of the State plan.
1903(u) Limitation of FFP for erroneous medical assistance expenditures.

§ 431.804 Definitions.

As used in this subpart—

Active case means an individual or family determined to be currently authorized as eligible for Medicaid by the agency.

Administrative period means the period of time recognized by the MEQC program for State agencies to reflect changes in case circumstances, i.e., a change in a common program area, during which no case error based on the circumstance change would be cited. This period consists of the review month and the month prior to the review month.

Claims processing error means FFP has been claimed for a Medicaid payment that was made—

(1) For a service not authorized under the State plan;

(2) To a provider not certified for participation in the Medicaid program;

(3) For a service already paid for by Medicaid; or

(4) In an amount above the allowable reimbursement level for that service.

Eligibility error means that Medicaid coverage has been authorized or payment has been made for a beneficiary or family under review who—

(1) Was ineligible when authorized or when he received services; or

(2) Was eligible for Medicaid but was ineligible for certain services he received; or

(3) Had not met beneficiary liability requirements when authorized eligible for Medicaid; that is, he had not incurred medical expenses equal to the amount of his excess income over the State's financial eligibility level or he had incurred medical expenses that exceeded the amount of excess income over the State's financial eligibility level, or was making an incorrect amount of payment toward the cost of services.

Negative case action means an action that was taken to deny or otherwise dispose of a Medicaid application without a determination of eligibility (for instance, because the application was withdrawn or abandoned) or an action to deny, suspend, or terminate an individual or family.

State agency means either the State Medicaid agency or a State agency that is responsible for determining eligibility for Medicaid.

§431.806 State plan requirements.

(a) *MEQC program.* A State plan must provide for operating a Medicaid eligibility quality control program that meets the requirements of §§431.810 through 431.822 of this subpart.

(b) *Use of PERM data.* A State plan must provide for operating a Medicaid eligibility quality control program that is in accordance with §431.978 through §431.988 of this part to meet the requirements of §431.810 through §431.822 of this subpart when a State is in their PERM year.

(c) *Claims processing assessment system.* Except in a State that has an approved Medicaid Management Information System (MMIS) under subpart C of part 433 of this subchapter, a State plan must provide for operating a Medicaid quality control claims processing assessment system that meets the requirements of §§431.830 through 431.836 of this subpart.

[55 FR 22166, May 31, 1990, as amended at 75 FR 48847, Aug. 11, 2010]

§431.808 Protection of beneficiary rights.

Any individual performing activities under the MEQC program or the claims processing assessment system specified in this subpart must do so in a manner that is consistent with the provisions of §§435.902 and 436.901 of this subchapter concerning the rights of beneficiaries.

MEDICAID ELIGIBILITY QUALITY CONTROL (MEQC) PROGRAM

SOURCE: Sections 431.810 through 431.822 appear at 55 FR 22167, May 31, 1990, unless otherwise noted.

§431.810 Basic elements of the Medicaid eligibility quality control (MEQC) program.

(a) *General requirements.* The agency must operate the MEQC program in accordance with this section and §§431.812 through 431.822 and other instructions established by CMS.

(b) *Review requirements.* The agency must conduct MEQC reviews in accordance with the requirements specified in §431.812 and other instructions established by CMS.

(c) *Sampling requirements.* The agency must conduct MEQC sampling in accordance with the requirements specified in §431.814 and other instructions established by CMS.

§431.812 Review procedures.

(a) *Active case reviews.* (1) Except as provided in paragraph (a)(2) of this section, the agency must review all active cases selected from the State agency's lists of cases authorized eligible for the review month, to determine if the cases were eligible for services during all or part of the month under review, and, if appropriate, whether the proper amount of beneficiary liability was computed.

(2) The agency is not required to conduct reviews of the following cases:

(i) Supplemental Security Income (SSI) beneficiary cases in States with

contracts under section 1634 of the Act for determining Medicaid eligibility.

(ii) Foster care and adoption assistance cases under title IV-E of the Act found eligible for Medicaid.

(iii) Cases under programs that are 100 percent federally funded.

(b) *Negative case reviews.* Except as provided in paragraph (c) of this section, or unless a State is utilizing an approved sampling plan to conduct negative case action reviews under § 431.978(a) and § 431.980(b), the agency must review those negative cases selected from the State agency's list of cases that are denied, suspended, or terminated in the review month to determine if the reason for the denial, suspension, or termination was correct and if requirements for timely notice of negative action were met. A State's negative case sample size is determined on the basis of the number of negative case actions in the universe.

(iv) Individuals whose eligibility was determined under a State's option under section 1902(e)(13) of the Act.

(c) *Alternate systems of negative case reviews*—(1) *Basic provision.* A State may be exempt from the negative case review requirements specified in paragraphs (b) and (e)(2) of this section and in § 431.814(d) upon CMS's approval of a plan for the use of a superior system.

(2) *Submittal of plan for alternate system.* An agency must submit its plan for the use of a superior system to CMS for approval at least 60 days before the beginning of the review period in which it is to be implemented. If a plan is unchanged from a previous period, the agency is not required to resubmit it.

The agency must receive approval for a plan before it can be implemented.

(3) *Requirement for alternate system.* To be approved, the State's plan must—

(i) Clearly define the purpose of the system and demonstrate how the system is superior to the current negative case review requirements.

(ii) Contain a methodology for identifying significant problem areas that could result in erroneous denials, suspensions, and terminations of applicants and beneficiaries. Problem areas selected for review must contain at least as many applicants and beneficiaries as were included in the negative case sample size previously required for the State.

(iii) Provide a detailed methodology describing how the extent of the problem area will be measured through sampling and review procedures, the findings expected from the review, and planned corrective actions to resolve the problem.

(iv) Include documentation supporting the use of the system methodology. Documentation must include the timeframes under which the system will be operated.

(v) Provide a superior means of monitoring denials, terminations, and suspensions than that required under paragraph (b) of this section.

(vi) Provide a statistically valid error rate that can be projected to the universe that is being studied.

(d) *Reviews for erroneous payments.* The agency must review all claims for services furnished during the review month and paid within 4 months of the review month to all members of each active case related in the sample to identify erroneous payments resulting from—

(1) Ineligibility for Medicaid;

(2) Ineligibility for certain Medicaid services; and

(3) beneficiary understated or overstated liability.

(e) *Reviews for verification of eligibility status.* The agency must collect and verify all information necessary to determine the eligibility status of each individual included in an active case selected in the sample as of the review month and whether Medicaid payments were for services which the individual was eligible to receive.

The agency must apply the administrative period described in § 431.804 when considering the case circumstances and the case correctness. In order to verify eligibility information, the agency must—

(1) Examine and analyze each case record for all cases under review to establish what information is available for use in determining eligibility in the review month;

(2) Conduct field investigations including in-person beneficiary interviews for each case in the active case sample, and conduct in-person interviews only when the correctness of the

agency action cannot be determined by review of the case record with beneficiaries for cases in the negative case action sample (unless this is otherwise addressed in a superior system provided for in paragraph (c)(1) of this section);

(3) Verify all appropriate elements of eligibility for active cases through at least one primary source of evidence or two secondary sources of evidence as defined by CMS by documentation or by collateral contacts as required, or both, and fully record the information on the appropriate forms;

(4) Determine the basis on which eligibility was established and the eligibility status of the active case and each case member;

(5) Collect copies of State paid claims or beneficiary profiles for services delivered during the review month and, if indicated, any months prior to the review month in the agency's selected spenddown period, for all members of the active case under review;

(6) Associate dollar values with eligibility status for each active case under review; and

(7) Complete the payment, case, and review information for all individuals in the active case under review on the appropriate forms.

(f) *Substitution of PERM data.*

(1) A State in its Payment Error Rate Measurement (PERM) year may elect to substitute the random sample of selected cases, eligibility review findings, and payment review findings obtained through PERM reviews conducted in accordance with §431.978 through §431.988 of this part for data required in this section, if the only exclusions are those set forth in §431.978(d)(1) of this part.

(2) PERM cases cited as undetermined may be dropped when calculating MEQC error rates if reasons for drops are acceptable reasons listed in the State Medicaid Manual.

[55 FR 22167, May 31, 1990, as amended at 72 FR 50513, Aug. 31, 2007; 75 FR 48847, Aug. 11, 2010]

§431.814 Sampling plan and procedures.

(a) *Plan approval.* The agency must submit a basic MEQC sampling plan (or revisions to a current plan) that meets the requirements of this section to the appropriate CMS regional office for approval at least 60 days before the beginning of the review period in which it is to be implemented. If a plan is unchanged from a previous period, the agency is not required to resubmit the entire plan. Universe estimates and sampling intervals are required 2 weeks before the first monthly sample selection for each review period. The agency must receive approval for a plan before it can be implemented.

(b) *Plan requirements.* The agency must have an approved sampling plan in effect for the full 6-month sampling period that includes the following:

(1) The population to be sampled;

(2) The list(s) from which the sample is selected and the following characteristics of the list(s):

(i) Sources;

(ii) All types of cases in the selection lists;

(iii) Accuracy and completeness of sample lists in reference to the population(s) of interest;

(iv) Whether or not the selection list was constructed by combining more than one list;

(v) The form of the selection list (whether the list or part of the list is automated);

(vi) Frequency and length of delays in updating the selection lists or their sources;

(vii) Number of items on the lists and proportion of listed-in-error items:

(viii) Methods of deleting unwanted items from the selection lists; and

(ix) Structure of the selection lists.

(3) The sample size, including the minimum number of reviews to be completed and the expected number of cases to be selected. Minimum sample sizes are based on the State's relative level of Medicaid annual expenditures for services for active cases, and on the total number of negative case actions in the universe for negative cases. When the sample is substratified, there can be no fewer than 75 cases in each substratum, except as provided in paragraph (c) of this section or as provided in an exception documented in an approved sampling plan which contains a statement accepting the precision and reliability of the reduced sample.

(4) The sample selection procedure. Systematic random sampling is recommended. Alternative procedures must provide a representative sample, conform to principles of probability sampling, and yield estimates with the same or better precision than achieved in systematic random sampling.

(5) Procedures used to identify amounts paid for services received in the review month.

(6) Specification as to whether the agency chooses to—

(i) Use billed amounts to offset beneficiary liability toward cost of care (No indication will be interpreted to mean that the agency will use paid claims); and

(ii) Use denied claims to offset beneficiary liability toward cost of care in the payment review. (No indication will be interpreted to mean denied claims will not be used.)

(7) Indication of whether the agency opts to drop or complete cases selected more than once in a sample period. (No indication will be interpreted to mean that the agency will complete cases selected more than once.)

(c) *Eligibility universe—active cases.* The MEQC universe for active cases must be divided into two strata, the Aid to Families with Dependent Children (AFDC) stratum and the Medical Assistance Only (MAO) stratum.

(1) All States must use the AFDC quality control sample for the AFDC stratum.

(2) States must include in the MAO stratum all cases certified as eligible for Medicaid that are not in the AFDC stratum, excluding individuals specified in paragraph (c)(4) of this section.

(3) States that do not have an agreement with the Social Security Administration under section 1634 of the Act and do not have more restrictive eligibility criteria under section 1902(f) of the Act but require a separate Medicaid application for beneficiaries of SSI and determine Medicaid eligibility using SSI criteria must divide the MAO stratum into two substrata: MAO cases and SSI cash cases for the first review period beginning after July 1, 1990 and for review periods thereafter. The SSI substratum sample size must be 75 cases or one-half of the total MAO sample, whichever is smaller. The non-SSI MAO substratum sample will be the remainder of the MAO stratum cases.

States may be exempt from this requirement when implementing an approved sampling option that does not accommodate this stratification method.

(4) States must exclude from the MEQC universe all of the following:

(i) SSI beneficiaries whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act.

(ii) Individuals in foster care or receiving adoption assistance whose eligibility is determined under Title IV–E of the Act.

(iii) Individuals receiving Medicaid under programs that are 100 percent Federally-funded.

(iv) Individuals whose eligibility was determined under a State's option for Express Lane Eligibility under section 1902(e)(13) of the Act.

(d) *Eligibility universe—negative cases.* Unless the agency has an approved superior system under §431.812(c) that provides otherwise, the universe for negative Medicaid eligibility cases must consist of all denied applications, suspensions, and terminations occurring during the review month except transfers between counties without any break in eligibility, cases in which eligibility is exclusively determined by SSA under a section 1634 contract, cases determined eligible for foster care and adoption assistance under title IV-E of the Act, and cases under programs that are 100 percent federally funded.

(e) *Sampling procedures.* The agency must document all sampling procedures used by the State agency, including 98 percent accuracy of program identifier codes used in the sampling frame to separate listed-in-error cases from those in the population of interest, must make them available for review by CMS, and must be able to demonstrate the integrity of its sampling procedures in accordance with this section.

(f) *Sampling periods.* The agency must use 6-month sampling periods, from April through September and from October through March.

(g) *Statistical samples.* The agency must select statistically valid samples of both active and negative case actions.

(h) *Sample selection lists.* The agency must submit to CMS monthly a list of cases selected in the sample to be reviewed, after the State's sample selection and before commencing MEQC reviews on the cases in the sample.

(i) *Universe estimates and sampling intervals.* The agency must submit detailed universe estimates and sampling intervals to CMS for approval at least 2 weeks before the first sample selection of the review period if the estimates differ from the previous period. The sampling intervals must be used continuously throughout the sampling period unless otherwise specified in an approved sampling plan. Final universe counts based on the actual sampling universe must be determined and reported to CMS for each stratum/substratum designated in the sampling plan.

The agency also must submit universe counts for cases eligible for foster care and adoption assistance under title IV-E of the Act, and, for States with an agreement under section 1634 of the Act, for cases found eligible by the Social Security Administration.

(j) *Sample size and methodology options.* The agency may select a sample size in accordance with the minimum established under paragraph (b)(3) of this section or use one of the methodologies specified in paragraph (j)(1) or (2) of this section.

(1) *Increase in size.* The agency may, at its option, increase its sample size for a sampling period above the federally prescribed minimum sample size provided for under paragraph (b)(3) of this section, and receive FFP for any increased administrative costs the agency incurs by exercising this option.

(2) *Retrospective sampling.* The agency may, at its option, implement retrospective sampling in which cases are stratified by dollar value of claims paid. If the agency selects retrospective sampling, it must—

(i) Draw an initial case sample size each month that is no less than 5 times the required sample size. The sample will be selected from the universe of cases that were certified eligible in the fourth month prior to the month of case selection;

(ii) Identify claims paid for services furnished to all individuals during the review month (and, if indicated, any months prior to the review month in the agency's selected spenddown period) for these cases;

(iii) Stratify the cases by dollar value of the claims into three strata; and

(iv) Select a second statistically valid sample within each group subject to the sample size requirements specified in paragraph (b)(3) or (j)(1) of this section.

[55 FR 22166, May 31, 1990, as amended at 75 FR 48847, Aug. 11, 2010]

§431.816 Case review completion deadlines and submittal of reports.

(a) The agency must complete case reviews and submit reports of findings to CMS as specified in paragraph (b) of this section in the form and at the time specified by CMS.

(b) In addition to the reporting requirements specified in §431.814 relating to sampling, the agency must complete case reviews and submit reports of findings to CMS in accordance with paragraphs (b)(1) through (6) of this section for review periods beginning after July 1, 1990. The agency must not combine or otherwise integrate case findings from the MAO and AFDC strata to meet the case percentage deadlines as specified in paragraphs (b)(1) through (6) of this section.

(1) *Active case eligibility reviews—MAO stratum.* (i) The agency must complete case eligibility reviews and report the findings electronically through the system prescribed by CMS for 90 percent of all active MAO cases within 105 days of the end of the review month for which those cases were reviewed, within 125 days for 95 percent of all active MAO cases, and within 150 days for 100 percent of all MAO active cases.

(ii) The agency must submit a report on cases selected for the review month.

(2) *Active case eligibility reviews—AFDC stratum.* (i) The agency must complete case eligibility reviews for AFDC ineligible and overpaid error cases caused by ineligible individuals and report the findings electronically

through the system prescribed by CMS within 105 days of the end of the review month for which those cases were reviewed for 90 percent of the total reviews; within 125 days of the end of the review month for which those cases were reviewed for 95 percent of the total reviews; and within 150 days of the end of the review month for which those cases were reviewed for 100 percent of the total reviews.

(ii) The agency must report findings electronically through the system prescribed by CMS for 100 percent of the State agency-reported eligible individuals within 30 days after the final timeframe required by the AFDC program as specified in program regulations at 45 CFR 205.40(b)(2)(ii).

(3) *Negative case eligibility reviews.* The agency must submit a monthly progress report on negative case reviews completed during the month unless the agency has an approved superior system in effect. The agency must submit a report on its findings by June 30 of each year for the previous April-September sampling period and by December 31, for the October-March sampling period.

(4) *Payment reviews.* (i) The agency must submit payment review findings electronically through the system prescribed by CMS.

(ii) The agency must complete payment review findings for 100 percent of the active case reviews in its sample and report the findings within 60 days after the first day of the month in which the claims collection process begins. The agency must wait 5 months after the end of each review month before associating the amount of claims paid for each case for services furnished during the review month unless retrospective sampling is elected.

(iii) The agency must make any necessary corrections to claims payments during the month the claim is paid and the following month. CMS will take necessary action to reject any State adjustment adversely affecting the error rate, for example, by not paying claims on error cases.

(5) *Summary of reviews and findings.* The agency must submit summary reports of the findings for all active cases in the 6-month sample by July 31 of each year for the previous April-September sampling period and by January 31 for the October-March sampling period. These summary reports must include findings changed in the Federal re-review process.

(6) *Other data and reports.* The agency must report other requested data and reports in a manner prescribed by CMS.

§ 431.818 Access to records: MEQC program.

(a) The agency, upon written request, must mail to the HHS staff all records, including complete local agency eligibility case files or legible copies and all other documents pertaining to its MEQC reviews to which the State has access, including information available under part 435, subpart I, of this chapter.

(b) The agency must mail requested records within 10 working days of receipt of a request, unless the State has an alternate method of submitting these records that is approved by CMS or has received, on an as-needed basis, approval from CMS to extend this timeframe by 3 additional working days to allow for exceptional circumstances.

§ 431.820 Corrective action under the MEQC program.

The agency must—

(a) Take action to correct any active or negative case action errors found in the sample cases;

(b) Take administrative action to prevent or reduce the incidence of those errors; and

(c) By September 15 each year, submit to CMS a report on its error rate analysis and a corrective action plan based on that analysis. The agency must submit revisions to the plan within 60 days of identification of additional error-prone areas, other significant changes in the error rate (that is, changes that the State experiences that increase or decrease its error rate and necessitate immediate corrective action or discontinuance of corrective actions that effectively control the cause of the error rate change), or changes in planned corrective action.

§ 431.822 Resolution of differences in State and Federal case eligibility or payment findings.

(a) When a difference exists between State and Federal case eligibility or payment findings, the Regional Office will notify the agency by a difference letter.

(b) The agency must return the difference letter to the Regional Office within 28 calendar days of the date of the letter indicating either agreement with the Federal finding or reasons for disagreement and if the agency desires a conference to resolve the difference. This period may be shortened if the Regional Office finds that it is necessary to do so in order to meet a case completion deadline, and the State still has a reasonable period of time in which to respond to the letter. If the agency fails to submit the difference letter indicating its agreement or disagreement with the Federal findings within the 28 calendar days (or the shorter period designated as described above), the Federal findings will be sustained.

(c) If the Regional Office disagrees with the agency's response, a difference conference will be scheduled within 20 days of the request of the agency. If a difference cannot be resolved, the State may request a direct presentation of its position to the Regional Administrator. The Regional Administrator has final authority for resolving the difference.

MEDICAID QUALITY CONTROL (MQC) CLAIMS PROCESSING ASSESSMENT SYSTEM

SOURCE: Sections 431.830 through 431.836 appear at 55 FR 22170, May 31, 1990, unless otherwise noted.

§ 431.830 Basic elements of the Medicaid quality control (MQC) claims processing assessment system.

An agency must—

(a) Operate the MQC claims processing assessment system in accordance with the policies, sampling methodology, review procedures, reporting forms, requirements, and other instructions established by CMS.

(b) Identify deficiencies in the claims processing operations.

(c) Measure cost of deficiencies;

(d) Provide data to determine appropriate corrective action;

(e) Provide an assessment of the State's claims processing or that of its fiscal agent;

(f) Provide for a claim-by-claim review where justifiable by data; and

(g) Produce an audit trail that can be reviewed by CMS or an outside auditor.

§ 431.832 Reporting requirements for claims processing assessment systems.

(a) The agency must submit reports and data specified in paragraph (b) of this section to CMS, in the form and at the time specified by CMS.

(b) Except when CMS authorizes less stringent reporting, States must submit:

(1) A monthly report on claims processing reviews sampled and or claims processing reviews completed during the month;

(2) A summary report on findings for all reviews in the 6-month sample to be submitted by the end of the 3rd month following the scheduled completion of reviews for that 6 month period; and

(3) Other data and reports as required by CMS.

§ 431.834 Access to records: Claims processing assessment systems.

The agency, upon written request, must provide HHS staff with access to all records pertaining to its MQC claims processing assessment system reviews to which the State has access, including information available under part 435, subpart J, of this chapter.

§ 431.836 Corrective action under the MQC claims processing assessment system.

The agency must—

(a) Take action to correct those errors identified through the claims processing assessment system review and, if cost effective, to recover those funds erroneously spent;

(b) Take administrative action to prevent and reduce the incidence of those errors; and

(c) By August 31 of each year, submit to CMS a report of its error analysis and a corrective action plan on the reviews conducted since the cut-off-date of the previous corrective action plan.

FEDERAL FINANCIAL PARTICIPATION

§§ 431.861–431.864 [Reserved]

§ 431.865 Disallowance of Federal financial participation for erroneous State payments (for annual assessment periods ending after July 1, 1990).

(a) *Purpose and applicability*—

(1) *Purpose.* This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous medical assistance payments due to eligibility and beneficiary liability errors, as detected through the Medicaid eligibility quality control (MEQC) program required under § 431.806 in effect on and after July 1, 1990.

(2) *Applicability.* This section applies to all States except Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa beginning July 1, 1990.

(b) *Definitions.* For purposes of this section—

Administrator means the Administrator, Centers for Medicare & Medicaid Services or his or her designee.

Annual assessment period means the 12-month period October 1 through September 30 and includes two 6-month sample periods (October-March and April-September).

Beneficiary liability means—

(1) The amount of excess income that must be offset with incurred medical expenses to gain eligibility; or

(2) The amount of payment a beneficiary must make toward the cost of services.

Erroneous payments means the Medicaid payment that was made for an individual or family under review who—

(1) Was ineligible for the review month or, if full month coverage is not provided, at the time services were received;

(2) Was ineligible to receive a service provided during the review month; or

(3) Had not properly met enrollee liability requirements prior to receiving Medicaid services.

(4) The term does not include payments made for care and services covered under the State plan and furnished to children during a presumptive eligibility period as described in § 435.1102 of this chapter.

National mean error rate means the payment weighted average of the eligibility payment error rates for all States.

National standard means a 3-percent eligibility payment error rate.

State payment error rate means the ratio of erroneous payments for medical assistance to total expenditures for medical assistance (less payments to Supplemental Security Income beneficiaries in section 1634 contract States and payments for children eligible for foster care and adoption assistance under title IV-E of the Act) for cases under review under the MEQC system for each assessment period.

Technical error means an error in an eligibility condition that, if corrected, would not result in a difference in the amount of medical assistance paid. These errors include work incentive program requirements, assignment of social security numbers, the requirement for a separate Medicaid application, monthly reporting requirements, assignment of rights to third party benefits, and failure to apply for benefits for which the family or individual is not eligible. Errors other than those listed in this definition, identified by CMS in subsequent instructions, or approved by CMS are not technical errors.

(c) *Setting of State's payment error rate.* (1) Each State must, for each annual assessment period, have a payment error rate no greater than 3 percent or be subject to a disallowance of FFP.

(2) A payment error rate for each State is determined by CMS for each annual assessment period by computing the statistical estimate of the ratio of erroneous payments for medical assistance made on behalf of individuals or cases in the sample for services received during the review month to total expenditures for medical assistance for that State made on behalf of individuals or cases in the sample for services received during the review month. This ratio incorporates the findings of a federally re-reviewed subsample of the State's review findings and is projected to the universe of total medical assistance payments for calculating the amount of disallowance under paragraph (d)6) of this section.

(3) The State's payment error rate does not include payments made on behalf of individuals whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act or children found eligible for foster care and adoption assistance under title IV-E of the Act.

(4) The amount of erroneous payments is determined as follows:

(i) For ineligible cases resulting from excess resources, the amount of error is the lesser of—

(A) The amount of the payment made on behalf of the family or individual for the review month; or

(B) The difference between the actual amount of countable resources of the family or individual for the review month and the State's applicable resources standard.

(ii) For ineligible cases resulting from other than excess resources, the amount of error is the total amount of medical assistance payments made for the individual or family under review for the review month.

(iii) For erroneous payments resulting from failure to properly meet beneficiary liability, the amount of error is the lesser of—

(A) The amount of payments made on behalf of the family or individual for the review month; or

(B) The difference between the correct amount of beneficiary liability and the amount of beneficiary liability met by the individual or family for the review month.

(iv) The amount of payments made for services provided during the review month for which the individual or family was not eligible.

(5) In determining the amount of erroneous payments, errors caused by technical errors are not included.

(6) If a State fails to cooperate in completing a valid MEQC sample or individual reviews in a timely and appropriate fashion as required, CMS will establish the State's payment error rate based on either—

(i) A special sample or audit;

(ii) The Federal subsample; or

(iii) Other arrangements as the Administrator may prescribe.

(7) When it is necessary for CMS to exercise the authority in paragraph (c)(6) of this section, the amount that would otherwise be payable to the State under title XIX of the Act is reduced by the full costs incurred by CMS in making these determinations. CMS may make these determinations either directly or under contractual or other arrangements.

(d) *Computation of anticipated error rate.* (1) Before the beginning of each quarter, CMS will project the anticipated medical assistance payment error rate for each State for that quarter. The anticipated error rate is the lower of the weighted average error rate of the two most recent 6-month review periods or the error rate of the most recent 6-month review period. In either case, cases in the review periods must have been completed by the State and CMS. If a State fails to provide CMS with information needed to project anticipated excess erroneous expenditures, CMS will assign the State an error rate as prescribed in paragraph (c)(6) of this section.

(2) If the State believes that the anticipated error rate established in accordance with paragraph (d)(1) of this section is based on erroneous data, the State may submit evidence that demonstrates the data were erroneous. If the State satisfactorily demonstrates that CMS's data were erroneous, the State's anticipated error rate will be adjusted accordingly. Submittal of evidence is subject to the following conditions:

(i) The State must inform CMS of its intent to submit evidence at least 70 days prior to the beginning of the quarter.

(ii) The State may request copies of data that CMS used to compute its anticipated error rate within 7 days of receiving notification of its projected error rate.

(iii) The State has up to 40 days before the quarter begins to present the evidence.

(iv) The evidence is restricted to documentation of suspected CMS data entry errors, processing errors, and resolutions of Federal subsample difference cases subsequent to calculation of the error rate projection as contained in the original notice to the State.

(v) The State may not submit other evidence, such as that consisting of revisions to State errors as a result of changes to the original State review findings submitted to CMS.

(vi) The State may not submit evidence challenging the error rate computational methodology.

(3) Based on the anticipated error rate established in paragraph (d)(1) or (d)(2) of this section, CMS reduces its estimate of the State's requirements for FFP for medical assistance for the quarter by the percentage by which the anticipated payment error rate exceeds the 3-percent national standard. This reduction is applied against CMS's total estimate of FFP for medical assistance expenditures (less payments to Supplemental Security Income beneficiaries in 1634 contract States and payments to children found eligible for foster care and adoption assistance under title IV-E of the Act) prior to any other required reductions. The reduction is noted on the State's grant award for the quarter and does not constitute a disallowance, and, therefore, is not appealable.

(4) After the end of each quarter, an adjustment to the reduction will be made based on the State's actual expenditures.

(5) After the actual payment error rate has been established for each annual assessment period, CMS will compute the actual amount of the disallowance and adjust the FFP payable to each State based on the difference between the amounts previously withheld for each of the quarters during the appropriate assessment period and the amount that should have been withheld based on the State's actual final error rate. If CMS determines that the amount withheld for the period exceeds the amount of the actual disallowance, the excess amount withheld will be returned to the States through the normal grant awards process within 30 days of the date the actual disallowance is calculated.

(6) CMS will compute the amount to be withheld or disallowed as follows:

(i) Subtract the 3-percent national standard from the State's anticipated or actual payment error rate percentage.

(ii) If the difference is greater than zero, the Federal medical assistance funds for the period, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively by the Social Security Administration under a section 1634 agreement and children found eligible for foster care and adoption assistance under title IV-E of the Act, are multiplied by that percentage. This product is the amount of the disallowance or withholding.

(7) A State's payment error rate for an annual assessment period is the weighted average of the payment error rates in the two 6-month review periods comprising the annual assessment period.

(8) The weights are established as the percent of the total annual payments, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively by the Social Security Administration under a section 1634 agreement and children found eligible for foster care and adoption assistance under title IV-E of the Act, that occur in each of the 6-month periods.

(e) *Notice to States and showing of good faith.* (1) When the actual payment error rate data are finalized for each annual assessment period ending after July 1, 1990, CMS will establish each State's error rate and the amount of any disallowance. States that have error rates above the national standard will be notified by letter of their error rates and the amount of the disallowance.

(i) The State has 65 days from the date of receipt of this notification to show that this disallowance should not be made because it failed to meet the national standard despite a good faith effort to do so.

(ii) If CMS is satisfied that the State did not meet the national standard despite a good faith effort, CMS may reduce the funds being disallowed in whole or in part as it finds appropriate under the circumstances shown by the State.

(iii) A finding that a State did not meet the national standard despite a good faith effort will be limited to extraordinary circumstances.

(iv) The burden of establishing that a good faith effort was made rests entirely with the State.

(2) Some examples of circumstances under which CMS may find that a State did not meet the national standard despite a good faith effort are—

(i) Disasters such as fire, flood, or civil disorders that—

(A) Require the diversion of significant personnel normally assigned to Medicaid eligibility administration; or

(B) Destroyed or delayed access to significant records needed to make or maintain accurate eligibility determinations;

(ii) Strikes of State staff or other government or private personnel necessary to the determination of eligibility or processing of case changes;

(iii) Sudden and unanticipated workload changes that result from changes in Federal law and regulation, or rapid, unpredictable caseload growth in excess of, for example, 15 percent for a 6-month period;

(iv) State actions resulting from incorrect written policy interpretations to the State by a Federal official reasonably assumed to be in a position to provide that interpretation; and

(v) The State has taken the action it believed was needed to meet the national standard, but the national standard was not met. CMS will consider request for a waiver under this criterion only if a State has achieved an error rate for the sample period that (after reducing the error rate by taking into account the cases determined by CMS to be in error as a result of conditions listed in paragraphs (e)(2) (i) through (iv) of this section) is less than its error rate for the preceding sample year and does not exceed the national mean error rate for the sample period under review (unless that national mean error rate is at or below the 3-percent national standard). If the agency has met this error reduction requirement or had error rates of 3 percent or below for the prior two review periods, and its error rate for the review period under consideration is less than one-third above the national standard, CMS will evaluate a request for a good faith waiver based on the following factors:

(A) The State has fully met the performance standards in the operation of a quality control system in accordance with Federal regulations and CMS guidelines (e.g., adherence to Federal case completion timeliness requirements and verification standards).

(B) The State has achieved substantial performance in the formulation of error reduction initiatives based on the following processes:

(*1*) Performance of an accurate and thorough statistical and program analysis for error reduction which utilized quality control and other data:

(*2*) The translation of such analysis into specific and appropriate error reduction practices for major error elements; and

(*3*) The use of monitoring systems to verify that the error reduction initiatives were implemented at the local office level.

(C) The State has achieved substantial performance in the operation of the following systems supported by evidence of the timely utilization of their outputs in the determination of case eligibility:

(*1*) The operation of the Income and Eligibility Verification System in accordance with the requirements of parts 431 and 435 of this chapter, and

(*2*) The operation of systems that interface with Social Security data and, where State laws do not restrict agency access, records from agencies responsible for motor vehicles, vital statistics, and State or local income and property taxes (where these taxes exist).

(D) The State has achieved substantial performance in the use of the following accountability mechanisms to ensure that agency staff adhere to error reduction initiatives. The following are minimum requirements:

(*1*) Accuracy of eligibility and liability determinations and timely processing of case actions are used as quantitative measures of employee performance and reflected in performance standards and appraisal forms:

(*2*) Selective second-party case reviews are conducted. The second-party review results are periodically reported to higher level management, as well as supervisors and workers and are used

in performance standards and appraisal forms; and

(*3*) Regular operational reviews of local offices are performed by the State to evaluate the offices' effectiveness in meeting error reduction goals with periodic monitoring to ensure that review recommendations have been implemented.

(vi) A State that meets the performance standards specified in paragraphs (e)(2)(v) (A) through (D) of this section will be considered for a full or partial waiver of its disallowance amount. The State must submit only specific documentation that verifies that the necessary actions were accomplished. For example, a State could submit worker performance standards reflecting timeliness and case accuracy as quantitative measures of performance.

(3) The failure of a State to act upon necessary legislative changes or to obtain budget authorization for needed resources is not a basis for finding that a State failed to meet the national standard despite a good faith effort.

(f) *Disallowance subject to appeal.* (1) If a State does not agree with a disallowance imposed under paragraph (e) of this section, it may appeal to the Departmental Appeals Board within 30 days from the date of the final disallowance notice from CMS. The regular procedures for an appeal of a disallowance will apply, including review by the Appeals Board under 45 CFR part 16.

(2) This appeal provision, as it applies to MEQC disallowances, is not applicable to the Administrator's decision on a State's waiver request provided for under paragraph (e) of this section.

[55 FR 22171, May 31, 1990, as amended at 61 FR 38398, July 24, 1996; 66 FR 2666, Jan. 11, 2001]

Subpart Q—Requirements for Estimating Improper Payments in Medicaid and CHIP

SOURCE: 71 FR 51081, Aug. 28, 2006, unless otherwise noted.

§ 431.950 Purpose.

This subpart requires States and providers to submit information necessary to enable the Secretary to produce national improper payment estimates for Medicaid and the Children's Health Insurance Program (CHIP).

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48847, Aug. 11, 2010]

§ 431.954 Basis and scope.

(a) *Basis.* The statutory bases for this subpart are as follows:

(1) Sections 1102, 1902(a)(6), and 2107(b)(1) of the Act, which contain the Secretary's general rulemaking authority and obligate States to provide information, as the Secretary may require, to monitor program performance.

(2) The Improper Payments Information Act of 2002 (Pub. L. 107–300), which requires Federal agencies to review and identify annually those programs and activities that may be susceptible to significant erroneous payments, estimate the amount of improper payments, report such estimates to the Congress, and submit a report on actions the agency is taking to reduce erroneous payments.

(3) Section 1902(a)(27)(B) of the Act requires States to require providers to agree to furnish the State Medicaid agencies and the Secretary with information regarding payments claimed by Medicaid providers for furnishing Medicaid services.

(4) Section 601 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3) which requires that the new PERM regulations include the following: Clearly defined criteria for errors for both States and providers; Clearly defined processes for appealing error determinations; clearly defined responsibilities and deadlines for States in implementing any corrective action plans; requirements for State verification of an applicant's self-declaration or self-certification of eligibility for, and correct amount of, medical assistance under Medicaid or child health assistance under CHIP; and State-specific sample sizes for application of the PERM requirements.

(b) *Scope.* (1) This subpart requires States under the statutory provisions cited in paragraph (a) of this section to submit information as set forth in § 431.970 for, among other purposes, estimating improper payments in the

fee-for-service (FFS) and managed care components of the Medicaid and CHIP programs and to determine whether eligibility was correctly determined. This subpart also requires providers to submit to the Secretary any medical records and other information necessary to disclose the extent of services provided to individuals receiving assistance, and to furnish information regarding any payments claimed by the provider for furnishing such services, as requested by the Secretary.

(2) All information must be furnished in accordance with section 1902(a)(7)(A) of the Act, regarding confidentiality.

(3) This subpart does not apply with respect to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands or American Samoa.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48847, Aug. 11, 2010]

§431.958 Definitions and use of terms.

Active case means a case containing information on a beneficiary who is enrolled in the Medicaid or CHIP program in the month that eligibility is reviewed.

Active fraud investigation means a beneficiary or a provider has been referred to the State Medicaid Fraud Control Unit or similar Federal or State investigative entity including a Federal oversight agency and the unit is currently actively pursuing an investigation to determine whether the beneficiary or the provider committed health care fraud. This definition applies to both the claims and eligibility review for PERM.

Adjudication date means either the date on which money was obligated to pay a claim or the date the decision was made to deny a claim.

Agency means, for purposes of the PERM eligibility reviews under this part, the entity that performs the Medicaid and CHIP eligibility reviews under PERM and excludes the State Medicaid or CHIP agency as defined in the regulation.

Annual sample size means the number of fee-for-service claims, managed care payments, or eligibility cases necessary to meet precision requirements in a given PERM cycle.

Application means an application form for Medicaid or CHIP benefits deemed complete by the State, with respect to which such State approved or denied eligibility.

Beneficiary means an applicant for, or beneficiary of, Medicaid or CHIP program benefits.

Case means an individual beneficiary or family enrolled in Medicaid or CHIP or who has been denied enrollment or has been terminated from Medicaid or CHIP. The case as a sampling unit only applies to the eligibility component.

Case error rate means an error rate that reflects the number of cases in error in the eligibility sample for the active cases plus the number of cases in error in the eligibility sample for the negative cases expressed as a percentage of the total number of cases examined in the sample.

Case record means either a hardcopy or electronic file that contains information on a beneficiary regarding program eligibility.

Children's Health Insurance Program (CHIP) means the program authorized and funded under Title XXI of the Act.

Eligibility means meeting the State's categorical and financial criteria for receipt of benefits under the Medicaid or CHIP programs.

Improper payment means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and includes any payment to an ineligible beneficiary, any duplicate payment, any payment for services not received, any payment incorrectly denied, and any payment that does not account for credits or applicable discounts.

Last action means the most recent date on which the State agency took action to grant, deny, or terminate program benefits based on the State agency's eligibility determination; and is the point in time for the PERM eligibility reviews unless the last action occurred outside of 12 months prior to the sample month.

Medicaid means the joint Federal and State program, authorized and funded under Title XIX of the Act, that provides medical care to people with low incomes and limited resources.

Negative case means a case containing information on a beneficiary who applied for benefits and was denied or whose program benefits were terminated, based on the State agency's eligibility determination or on a completed redetermination.

Payment means any payment to a provider, insurer, or managed care organization for a Medicaid or CHIP beneficiary for which there is Medicaid or CHIP Federal financial participation. It may also mean a direct payment to a Medicaid or CHIP beneficiary in limited circumstances permitted by CMS regulation or policy.

Payment error rate means an annual estimate of improper payments made under Medicaid and CHIP equal to the sum of the overpayments and underpayments in the sample, that is, the absolute value of such payments, expressed as a percentage of total payments made in the sample.

Payment review means the process by which payments for services are associated with cases reviewed for eligibility. Payments are collected for services received in the review month or in the sample month, depending on the case reviewed.

PERM means the Payment Error Rate Measurement process to measure improper payment in Medicaid and CHIP.

Provider means any qualified provider recognized under Medicaid and CHIP statute and regulations.

Provider error includes, but is not limited to, medical review errors as described in § 431.960(c) of this subpart, as determined in accordance with documented State or Federal policies or both.

Review cycle means the complete timeframe to complete the improper payments measurement including the fiscal year being measured; generally this timeframe begins in October of the fiscal year reviewed and ends in August of the following fiscal year.

Review month means the month in which eligibility is reviewed and is usually when the State took its last action to grant or redetermine eligibility. If the State's last action was taken beyond 12 months prior to the sample month, the review month shall be the sample month.

Review year means the Federal fiscal year being analyzed for errors by Federal contractors or the State.

Sample month means the month the State selects a case from the sample for an eligibility review.

State agency means the State agency that is responsible for determining program eligibility for Medicaid and CHIP, as applicable, based on applications and redeterminations.

State error includes, but is not limited to, data processing errors and eligibility errors as described in § 431.960(b) and (d) of this subpart, as determined in accordance with documented State or Federal policies or both.

States means the 50 States and the District of Columbia.

Undetermined means a beneficiary case subject to a Medicaid or CHIP eligibility determination under this regulation about which a definitive determination of eligibility could not be made.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48847, Aug. 11, 2010]

§ 431.960 Types of payment errors.

(a) *General rule.* State or provider errors identified for the Medicaid and CHIP improper payments measurement under the Improper Payments Information Act of 2002 must affect payment under applicable Federal policy or State policy or both.

(b) *Data processing errors.*

(1) A data processing error is an error resulting in an overpayment or underpayment that is determined from a review of the claim and other information available in the State's Medicaid Management Information System, related systems, or outside sources of provider verification.

(2) The difference in payment between what the State paid (as adjusted within improper payment measurement guidelines) and what the State should have paid, in accordance with the State's documented policies, is the dollar measure of the payment error.

(3) Data processing errors include, but are not limited to the following:

(i) Payment for duplicate items.

(ii) Payment for non-covered services.

(iii) Payment for fee-for-service claims for managed care services.

(iv) Payment for services that should have been paid by a third party but were inappropriately paid by Medicaid or CHIP.

(v) Pricing errors.

(vi) Logic edit errors.

(vii) Data entry errors.

(viii) Managed care rate cell errors.

(ix) Managed care payment errors.

(c) *Medical review errors.* (1) A medical review error is an error resulting in an overpayment or underpayment that is determined from a review of the provider's medical record or other documentation supporting the service(s) claimed, Code of Federal Regulations that are applicable to conditions of payment, the State's written policies, and a comparison between the documentation and written policies and the information presented on the claim.

(2) The difference in payment between what the State paid (as adjusted within improper payment measurement guidelines) and what the State should have paid, in accordance with 42 CFR 440 to 484.55 of the Code of Federal Regulations that are applicable to conditions of payment and the State's documented policies, is the dollar measure of the payment error.

(3) Medical review errors include, but are not limited to the following:

(i) Lack of documentation.

(ii) Insufficient documentation.

(iii) Procedure coding errors.

(iv) Diagnosis coding errors.

(v) Unbundling.

(vi) Number of unit errors.

(vii) Medically unnecessary services.

(viii) Policy violations.

(ix) Administrative errors.

(d) *Eligibility errors.* (1) An eligibility error includes, but is not limited to, errors determined by applying Federal rules and the State's documented policies and procedures, resulting from services being provided to an individual who meets at least one of the following provisions:

(i) Was ineligible when authorized as eligible or when he or she received services.

(ii) Was eligible for the program but was ineligible for certain services he or she received.

(iii) Lacked or had insufficient documentation in his or her case record, in accordance with the State's documented policies and procedures, to make a definitive review decision of eligibility or ineligibility.

(iv) Overpaid the assigned liability due to the individual's liability being understated.

(v) Underpaid toward assigned liability due to the individual's liability being overstated.

(vi) Was ineligible for managed care but enrolled in managed care.

(vii) Was eligible for managed care but improperly enrolled in the incorrect managed care plan.

(2) The dollars paid in error due to the eligibility error is the measure of the payment error.

(3) A State eligibility error does not result from the State's verification of an applicant's self-declaration or self-certification of eligibility for, and the correct amount of, medical assistance or child health assistance, if the State process for verifying an applicant's self-declaration or self-certification satisfies the requirements in Federal law, guidance, or if applicable, Secretary approval.

(4) Negative case errors are errors, based on the State's documented policies and procedures, resulting from either of the following:

(i) Applications for Medicaid or CHIP that are improperly denied by the State.

(ii) Existing cases that are improperly terminated from Medicaid or CHIP by the State.

(5) No payment errors are associated with negative cases.

(e) *Errors for purposes of determining the national error rates.* The Medicaid and CHIP national error rates include but are not limited to the errors described in paragraphs (b) through (d) of this section, with the exception of negative case errors described in paragraph (d)(4) of this section.

(f) *Errors for purposes of determining the State error rates.* The Medicaid and CHIP State error rates include but are not limited to, the errors described in paragraphs (b) through (d)(1)(vii) of this section, with the exception of negative case errors as described in paragraph (d)(4) of this section.

(g) *Error codes.* CMS may define different types of errors within the above categories for analysis and reporting

purposes. Only dollars in error will factor into a State's PERM error rate.

[75 FR 48848, Aug. 11, 2010]

§ 431.970 Information submission requirements.

(a) States must submit information to the Secretary for, among other purposes, estimating improper payments in Medicaid and CHIP, that include but are not limited to—

(1) Adjudicated fee-for-service (FFS) or managed care claims information or both, on a quarterly basis, from the review year;

(2) Upon request from CMS, provider contact information that has been verified by the State as current;

(3) All medical and other related policies in effect and any quarterly policy updates;

(4) Current managed care contracts, rate information, and any quarterly updates applicable to the review year for CHIP and, as requested, for Medicaid;

(5) Data processing systems manuals;

(6) Repricing information for claims that are determined during the review to have been improperly paid;

(7) Information on claims that were selected as part of the sample, but changed in substance after selection, for example, successful provider appeals;

(8) Adjustments made within 60 days of the adjudication dates for the original claims or line items with sufficient information to indicate the nature of the adjustments and to match the adjustments to the original claims or line items;

(9) For the eligibility improper payment measurement, information as set forth in §§ 431.978 through 431.988;

(10) A corrective action plan for purposes of reducing erroneous payments in FFS, managed care, and eligibility; and

(11) Other information that the Secretary determines is necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and CHIP.

(b) Providers must submit information to the Secretary for, among other purposes estimating improper payments in Medicaid and CHIP, which include but are not limited to, Medicaid and CHIP beneficiary medical records within 75 calendar days of the date the request is made by CMS. If CMS determines that the documentation is insufficient, providers must respond to the request for additional documentation within 14 calendar days of the date the request is made by CMS.

[71 FR 51081, Aug. 28, 2006, as amended at 72 FR 50513, Aug. 31, 2007; 75 FR 48848, Aug. 11, 2010]

§ 431.972 Claims sampling procedures.

(a) *Claims universe.* (1) The PERM claims universe includes payments that were originally paid (paid claims) and for which payment was requested but denied (denied claims) during the FFY, and for which there is FFP (or would have been if the claim had not been denied) through Title XIX (Medicaid) or Title XXI (CHIP).

(2) The State must establish controls to ensure FFS and managed care universes are accurate and complete, including comparing the FFS and managed care universes to the Form CMS–64 and Form CMS–21 as appropriate.

(b) *Sample size.* CMS estimates a State's annual sample size for claims review at the beginning of the PERM cycle.

(1) *Precision and confidence levels.* The annual sample size should be estimated to achieve a State-level error rate within a 3 percent precision level at 95 percent confidence interval for the claims component of the PERM program, unless the precision requirement is waived by CMS on its own initiative.

(2) *Base year sample size.* The annual sample size in a State's first PERM cycle (the ''base year'') is—

(i) Five hundred fee-for-service claims and 250 managed care payments drawn from the claims universe; or

(ii) If the claims universe of fee-for-service claims or managed care capitation payments from which the annual sample is drawn is less than 10,000, the State may request to reduce its sample size by the finite population correction factor for the relevant PERM cycle.

(3) *Subsequent year sample size.* In PERM cycles following the base year:

(i) CMS considers the error rate from the State's previous PERM cycle to determine the State's annual sample size for the current PERM cycle.

(ii) The maximum sample size is 1,000 fee-for-service or managed care payments, respectively.

(iii) If a State measured in the FY 2007 or FY 2008 cycle elects to reject its State-specific CHIP PERM rate determined during those cycles, information from those cycles will not be used to calculate its annual sample size in subsequent PERM cycles and the State's annual sample size in its base year is 500 fee-for-service and 250 managed care payments.

[75 FR 48849, Aug. 11, 2010]

§431.974 Basic elements of Medicaid and CHIP eligibility reviews.

(a) *General requirements.* (1) States selected in any given year for Medicaid and CHIP improper payments measurement under the Improper Payments Information Act of 2002 must conduct reviews of a statistically valid random sample of beneficiary cases for such programs to determine if improper payments were made based on errors in the State agency's eligibility determinations.

(2) The agency and personnel responsible for the development, direction, implementation, and evaluation of the eligibility reviews and associated activities, including calculation of the error rates under this section, must be functionally and physically separate from the State agencies and personnel that are responsible for Medicaid and CHIP policy and operations, including eligibility determinations.

(3) Any individual performing activities under this section must do so in a manner that is consistent with the provisions of §435.901, concerning the rights of beneficiaries.

(b) *Sampling requirements.* The State must have in effect a CMS-approved sampling plan for the review year in accordance with the requirements specified in §431.978.

(c) *Review requirements.* The State must conduct eligibility reviews in accordance with the requirements specified in §431.980.

§431.978 Eligibility sampling plan and procedures.

(a) *Plan approval.* For each review year, the agency must—

(1) Submit its Medicaid or CHIP sampling plan (or revisions to a current plan) for both active and negative cases to CMS for approval by the August 1 before the review year; and

(2) Have its sampling plan approved by CMS before the plan is implemented.

(b) *Maintain current plan.* The agency must do both of the following:

(1) Keep its plan current, for example, by making adjustments to the plan when necessary due to fluctuations in the universe.

(2) Review its plan each review year. If it is determined that the approved plan is—

(i) Unchanged from the previous review year, the agency must notify CMS that it is using the plan from the previous review year; or

(ii) Changed from the previous review year, the agency must submit a revised plan for CMS approval.

(c) *Sample size.*

(1) *Precision and confidence levels.* Annual sample size for eligibility reviews should be estimated to achieve within a 3 percent precision level at 95 percent confidence interval for the eligibility component of the program.

(2) *Base year sample size.* Annual sample size for each State's base year of PERM is—

(i) Five hundred four active cases and 204 negative cases drawn from the active and negative universes; or

(ii) If the active case universe or negative case universe of Medicaid or CHIP beneficiaries from which the annual sample is drawn is less than 10,000, the State may request to reduce its sample size by the finite population correction factor for the relevant PERM cycle.

(3) *Subsequent year sample size.* In PERM cycles following the base year the annual sample size may increase or decrease based on the State's prior results of the previous cycle PERM error rate information. The State may provide information to CMS in the eligibility sampling plan due to CMS by the August 1 prior to the start of the review year to support the calculation of a reduced annual sample size for the next PERM cycle.

(i) CMS considers the error rate from the State's previous PERM cycle to determine the State's annual sample size for the current PERM cycle.

(ii) The maximum sample size is 1,000 for the active cases and negative cases, respectively.

(iii) If the active case universe or negative case universe of Medicaid or CHIP beneficiaries from which the annual sample is drawn is less than 10,000, the State may request to reduce its sample size by the finite population correction factor for the relevant PERM cycle.

(iv) If a State measured in the FY 2007 or FY 2008 cycle elects to reject its PERM CHIP rate as determined during those cycles, information from those cycles is not used to calculate the State's sample size in subsequent PERM cycles and the State's sample size in its base year is 504 active cases and 204 negative cases.

(d) *Sample selection*. The sample must be stratified in accordance with § 431.978(d)(3). Cases must be selected each month throughout the fiscal year under review. Each month throughout the year and before commencing the eligibility reviews, States must submit to CMS a monthly sample selection list that identifies the cases selected in that month.

(1) *Eligibility universe-active cases*—(i) *Medicaid*. (A) The Medicaid active universe consists of all active Medicaid cases funded through Title XIX for the sample month.

(B) The following types of cases are excluded from the Medicaid active universe:

(*1*) Cases for which the Social Security Administration, under section 1634 of the Act agreement with a State, determines Medicaid eligibility for Supplemental Security Income beneficiaries.

(*2*) All foster care and adoption assistance cases under Title IV–E of the Act are excluded from the universe in all States.

(*3*) Cases under active fraud investigation.

(*4*) Cases in which eligibility was determined under section 1902(e)(13) of the Act for States' Express Lane Eligibility option.

(C) If the State cannot identify cases that meet the exclusion criteria specified in paragraph (d)(1)(i)(B) of this section before sample selection, the State must drop these cases from review if they are selected in the sample and are later determined to meet the exclusion criteria specified in paragraph (d)(1)(i)(B) of this section.

(ii) *CHIP*. (A) The CHIP active universe consists of all active case CHIP and Title XXI Medicaid expansion cases that are funded through Title XXI for the sample month.

(B) The following types of cases are excluded from the CHIP active universe:

(*1*) Cases under active fraud investigation.

(*2*) Cases in which eligibility was determined under section 2107(e)(1) of the Act for States' Express Lane Eligibility option.

(C) If the State cannot identify cases that meet the exclusion criteria specified in paragraph (d)(1)(ii)(B) of this section before sample selection, the State must drop these cases from review if it is later determined that the cases meet the exclusion criteria specified in paragraph (d)(1)(ii)(B) of this section.

(2) *Eligibility universe—negative cases*. The Medicaid and CHIP negative universe consists of all negative cases for the sample month. The negative case universe is not stratified.

(3) *Stratifying the universe*. States have the option to stratify the active case universe.

(i) Each month, the State may stratify the Medicaid and CHIP active case universe into three strata:

(A) Program applications completed by the beneficiaries in which the State took action in the sample month to approve such beneficiaries for Medicaid or CHIP based on the eligibility determination.

(B) Redeterminations of eligibility in which the State took action in the sample month to approve the beneficiaries for Medicaid or CHIP based on information obtained through a completed redetermination.

(C) All other cases.

(ii) States that do not stratify the universe will sample from the entire active case universe each month.

(4) *Sample selection.* Each month, an equal number of cases are selected for review from one of the following:

(i) Each stratum as described in paragraph (d)(3)(i) of this section.

(ii) The entire active case universe if opting not to stratify cases under paragraph (d)(2)(ii) of this section.

(iii) Otherwise provided for in the State's sampling plan approved by CMS.

[71 FR 51081, Aug. 28, 2006, as amended at 72 FR 50513, Aug. 31, 2007; 75 FR 48849, Aug. 11, 2010]

§ 431.980 Eligibility review procedures.

(a) *Active case reviews.* The agency must verify eligibility for all selected active cases for Medicaid and CHIP for the review month for compliance with the State's eligibility criteria.

(b) *Negative case reviews.* The agency must review all selected negative cases for Medicaid and CHIP for the review month to determine whether the cases were properly denied or terminated.

(c) *Payment review.* The agency must identify all Medicaid and CHIP payments made for services furnished, either in the first 30 days of eligibility or in the review month for applications under § 431.978(d)(3)(i) and redeterminations under § 431.978(d)(3)(ii) in accordance to State policy or from the sample month for all other cases under § 431.978(d)(3)(iii), to identify erroneous payments resulting from ineligibility for services or for the program.

(d) *Eligibility review decision*—(1) *Active cases—Medicaid.* Unless the State has selected to substitute MEQC data for PERM data under paragraph (f) of this section, the agency must complete all of the following:

(i) Review the cases specified at §§ 431.978(d)(3)(i)(A) and 431.978(d)(3)(i)(B) of this subpart in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the review month and identify payments made on behalf of such beneficiary or family for services received in the first 30 days of eligibility.

(ii) For cases specified in § 431.978(d)(3)(i)(C) of this subpart, review the last action as follows:

(A) If the last action was not more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the last action and identify payments made on behalf of such beneficiary or family in the first 30 days of eligibility.

(B) If the last action occurred more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the sample month and identify payments made on behalf of the beneficiary or family for services received in the sample month.

(iii) For cases in States that do not stratify the universe, as specified in § 431.978(d)(3)(ii) of this subpart, review the last action as follows:

(A) If the last action was no more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the last action and identify payments made on behalf of such beneficiary or family for services received in the sample month.

(B) If the last action occurred more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria, and documented policies and procedures, as of the sample month and identify payments made on behalf of the beneficiary or family for services received in the sample month.

(C) Cases that are not stratified must have the last action identified as either falling under the criteria of § 431.978(d)(3)(i)(A) or § 431.978(d)(3)(i)(B) of this subpart after the sample is selected.

(iv) Examine the evidence in the case file that supports categorical and financial eligibility for the category of coverage in which the case is assigned, and independently verify information that is missing, outdated (older than 12 months) and likely to change, or otherwise as needed, to verify eligibility.

(v) For managed care cases, also verify residency and eligibility for and actual enrollment in the managed care plan during the month under review.

(vi) Elements of eligibility in which State policy allows for self-declaration or self-certification are considered to

be verified with a self-declaration or self-certification statement. The self-declaration or self-certification must be—

(A) Present in the record;

(B) Not outdated (more than 12 months old);

(C) Originating from the last case action that was not more than 12 months prior to the sample month;

(D) In a valid, State-approved format; and

(E) Consistent with other facts in the case record.

(vii) If a self-declaration or self-certification statement does not meet the provisions of paragraphs (e)(1)(vi)(A) through (D) of this section, eligibility may be verified through a new self-declaration or self-certification statement or other third party sources.

(A) If eligibility or ineligibility cannot be verified, cite a case as undetermined.

(ix) As a result of paragraphs (e)(1)(i) through (e)(1)(vii) of this section—

(A) Cite the case as eligible or ineligible based on the review findings and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the first 30 days of eligibility, the review month, or sample month, as appropriate; or

(B) Cite the case as undetermined if after due diligence an eligibility determination could not be made and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the first 30 days of eligibility, the review month or sample month, as appropriate.

(2) *Active cases—CHIP.* In addition to the procedures for active cases as set forth in paragraphs (e)(1)(i) through (e)(1)(vii) of this section, the agency must verify that the case is not eligible for Medicaid by determining that the child has income above the Medicaid levels in accordance with the requirements in § 457.350 of this chapter. Upon verification, the agency must—

(e) *Negative cases—Medicaid and CHIP.* The agency must—

(1) Identify the reason the State agency determined ineligibility;

(2) Examine the evidence in the case file to determine whether the State agency's denial or termination was correct or whether there is any reason the case should have been denied or terminated; and

(i) Record the State agency's finding as correct if the case record review substantiates that the individual was not eligible; or

(ii) Record the case as an error if there is no valid reason for the denial or termination.

(f) *Substitution of MEQC data.* (1) A State in their PERM year may elect to substitute the random sample of selected cases, eligibility review findings, and payment review findings, as qualified by paragraphs (d)(2) and (d)(3) of this section, which are obtained through MEQC reviews conducted in accordance with section 1903(u) of the Act for data required in this section, as long as the State MEQC reviews meet the requirements of the MEQC Sampling Plan and Procedures at § 431.814 of this part, and if the only exclusions are those set forth in section 1902(e)(13) of the Act, § 431.814(c)(4), and § 431.978(d)(1) of this part.

(2) MEQC samples must also meet PERM confidence and precision requirements.

(3) MEQC cases that are dropped due to the acceptable reasons listed in the State Medicaid Manual are included in the PERM error rate calculation.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48850, Aug. 11, 2010]

§ 431.988 Eligibility case review completion deadlines and submittal of reports.

(a)(1) States must complete and report to CMS the findings, including total number of cases in the eligibility universe, the error causes for all case reviews listed on the monthly sample selection lists, including cases dropped from review due to active fraud investigations, and cases for which eligibility could not be determined.

(2) States must submit a summary report of the active case eligibility and payment review findings to CMS by July 1 following the review year.

(b) The agency must report by July 1 following the review year, information as follows:

(1) Case and payment error data for active cases.

(2) Case error data for negative cases.

(3) Identify the last action on a case, either application or redetermination for States that do not stratify the eligibility sample in accordance with §431.978(d)(3)(i) of this subpart.

(4) The number and amounts of undetermined cases in the sample and the total amount of payments from all undetermined cases.

(5) The number of cases dropped from review due to active fraud investigations.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48851, Aug. 11, 2010]

§431.992 Corrective action plan.

(a) The State agency must develop a separate corrective action plan for Medicaid and CHIP, which is not required to be approved by CMS, designed to reduce improper payments in each program based on its analysis of the error causes in the FFS, managed care, and eligibility components.

(b) In developing a corrective action plan, the State must take the following actions:

(1) *Data analysis.* States must conduct data analysis such as reviewing clusters of errors, general error causes, characteristics, and frequency of errors that are associated with improper payments.

(2) *Program analysis.* States must review the findings of the data analysis to determine the specific programmatic causes to which errors are attributed (for example, provider lack of understanding of the requirement to provide documentation) and to identify root error causes.

(3) *Corrective action planning.* States must determine the corrective actions to be implemented that address the root error causes.

(4) *Implementation and monitoring.*

(i) States must develop an implementation schedule for each corrective action initiative and implement those actions in accordance with the schedule.

(ii) The implementation schedule must identify all of the following:

(A) Major tasks.

(B) Key personnel responsible for each activity.

(C) A timeline for each action including target implementation dates, milestones, and monitoring.

(5) *Evaluation.* States must evaluate the effectiveness of the corrective action by assessing all of the following:

(i) Improvements in operations.

(ii) Efficiencies.

(iii) Number of errors.

(iv) Improper payments.

(c) The State agency must submit to CMS and implement the corrective action plan for the fiscal year it was reviewed no later than 90 calendar days after the date on which the State's Medicaid or CHIP error rates are posted on the CMS contractor's Web site.

(d) The State must submit to CMS a new corrective action plan for each subsequent error rate measurement that contains an update on the status of a previous corrective action plan. Items to address in the new corrective action plan include, but are not limited to the following:

(1) Effectiveness of implemented corrective actions, as assessed using objective data sources.

(2) Discontinued or ineffective actions, actions not implemented, and those actions, if any, that were substituted for such discontinued, ineffective, or abandoned actions.

(3) Findings on short-term corrective actions.

(4) The status of the long-term corrective actions.

[75 FR 48851, Aug. 11, 2010]

§431.998 Difference resolution and appeal process.

(a) The State may file, in writing, a request with the Federal contractor to resolve differences in the Federal contractor's findings based on medical or data processing reviews on FFS and managed care claims in Medicaid or CHIP within 20 business days after the disposition report of claims review findings is posted on the contractor's Web site. The State must complete all of the following:

(1) Have a factual basis for filing the difference.

(2) Provide the Federal contractor with valid evidence directly related to the error finding to support the State's position that the claim was properly paid.

(b) For a claim in which the State and the Federal contractor cannot resolve the difference in findings, the

State may appeal to CMS for final resolution, filing the appeal within 10 business days from the date the contractor's finding as a result of the difference resolution is posted on the contractor's Web site. There is no minimum dollar threshold required to appeal a difference in findings.

(c) For eligibility error determinations made by the agency with personnel functionally and physically separate from the State Medicaid and CHIP agencies with personnel that are responsible for Medicaid and CHIP policy and operations, the State may appeal error determinations by filing an appeal request.

(1) *Filing an appeal request.* The State may—

(i) File its appeal request with the appropriate State agency or entity; or

(ii) If no appeals process is in place at the State level, differences in findings—

(A) Must be documented in writing and submitted directly to the agency responsible for the PERM eligibility review for its consideration;

(B) May be resolved through document exchange facilitated by CMS, whereby CMS will act as intermediary by receiving the written documentation supporting the State's appeal from the State agency and submitting that documentation to the agency responsible for the PERM eligibility review; or

(C) Any unresolved differences may be addressed by CMS between the final month of payment data submission and error rate calculation.

(2) *After the filing of an appeals request.* (i) Any changes in error findings must be reported to CMS by the deadline for submitting final eligibility review findings.

(ii) Any appeals of determinations based on interpretations of Federal policy may be referred to CMS.

(iii) CMS's eligibility error resolution decision is final.

(iv) If CMS's or the State-level appeal board's decision causes an erroneous payment finding to be made, if the final adjudicated claim is actually a payment error in accordance with documented State policies and procedures, any resulting recoveries are governed by § 431.1002 of this subchapter.

(d) All differences, including those pending in CMS for final decision that are not resolved in time to be included in the error rate calculation, will be considered as errors for meeting the reporting requirements of the IPIA. Upon State request, CMS will calculate a subsequent State-specific error rate that reflects any reversed disposition of the unresolved claims.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48851, Aug. 11, 2010]

§ 431.1002 Recoveries.

(a) *Medicaid.* States must return to CMS the Federal share of overpayments based on medical and processing errors in accordance with section 1903(d)(2) of the Act and related regulations at part 433, subpart F of this chapter. Payments based on erroneous Medicaid eligibility determinations are addressed under section 1903(u) of the Act and related regulations at part 431, subpart P of this chapter.

(b) *CHIP.* Quarterly Federal payments to the States under Title XXI of the Act must be reduced in accordance with section 2105(e) of the Act and related regulations at part 457, subpart B of this chapter.

PART 432—STATE PERSONNEL ADMINISTRATION

Subpart A—General Provisions

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